O P E R A T I N G I N S T R U C T I O N S

K S G FLASH - 2

Table top unit

with

microprocessor command

Modifications reserved.	01.06.10
Article No.:	Aukl 002 96 - left
Order-No.:	184763
Serial-No.:	7897
Electric-Diagram	04E00BLI001
Piping Diagram	04R00BLI001

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1. Introduction

1.1. Operating instructions

Please read the operating instructions carefully and completely and assure that you have understood the directions and are able to act accordingly. When using the sterilizer, you always have to act acc. to the operating instructions. One set of the instructions should always be at the sterilizer. In case of any questions, please contact the technicians of Messrs. KSG.

The operating instructions are part of the apparatus documentation and thus inseparably allocated to the apparatus.

Note: Corresponding to the additional contract conditions – Sterilizers/Water stills 01.98 – Contract Procedure for constructional effects and Contract Procedure for deliveries (*EVB STER/DES 01.98 -VOB and VOL)- Effects for instruction point 6.2* the use of steam sterilizers is only allowed to persons who have been trained on the apparatus and know about possible dangers in case of unskilled behaviour.

The standard operating instructions for **KSG FLASH-2** with microprocessor command do not contain specific modifications and additional equipment, as central reverse-osmosis units, central water stills or similar units for preparation of boiler feed water replacing the demineralizing unit, which can be included or automatic feeding devices for the storage tank. Information concerning such devices should be received from the user.

1.2. Apparatus Name

KSG FLASH-2
Article No.: Aukl 002 96 - left
Order-No.: 184763
Serial-No.: 7897
Year of construction: 2010

1.3. Manufacturer

KSG Sterilisatoren GmbH
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E-Mail: service@ksg-sterilisatoren.de

1.4. Customer Service

Information concerning the corresponding service company can be obtained at the central phone No.: +49-(0)8141 / 354528- 0.

2. Use

2.1. Intended use of the unit

Sterilizer Type **KSG FLASH-2** in this model may only be used for sterilization of **solid** and **porous**, **packed** and **not packed** goods with a sterilisation temperature of 134° C as well as from **solid** and **porous**, **packed** and **not packed** goods with a sterilisation temperature of 121° C are used.

Solutions, independent from the size of the receptacles, may not be sterilized in this sterilizer.

In no case inflammable materials may be sterilized.

No living beings may be sterilized.

The device is not been suitable for the sterilisation (destruction) by the lab goods which were submitted to a **chemical and** / **or biological** treatment. Such treated goods may **not** be sterilized.

2.2. Intended aim

The aim of sterilization is the achievement of the sterility of a sterilizer load (charge) acc. to the sterilizing process.

Hint: Sterile is the condition of a medical product, which is free from active micro organisms (EN 556).

3. Safety measurements

3.1. General Danger when the safety hints are not adhered to

The apparatus is safe and constructed according to the actual state of the art. Before delivery a comprehensive examination on function and safety has taken place. Nevertheless there is danger for the operator or injures to the efficiency of the unit, if it is operated by unskilled staff and/or used improperly for another purpose. Furthermore there is the danger that the efficiency of the unit is influenced resp. that the unit or parts thereof are disturbed (DIN 58946-6 – 04-2002 – 6).

Each person, which is operating, maintaining and repairing the unit, must have read and understood the operating instructions and especially paragraph *Safety measurements*. We recommend to the user to establish directions in his company under consideration of the qualification of the staff. He should order that his staff gives a written confirmation upon receipt of these directions (DIN 58946-6 – 04-2002 – 4, 5).

3.2. Safe working

The apparatus may only be used by skilled and authorized staff.

The daily, weekly and monthly maintenance and inspection works can be executed by the trained persons. The maintenance and inspection works to be done every six months are should be carried out by KSG or a service company authorized by KSG. (see maintenance and check lists). This is especially applicable for works at the electrical, pneumatically and hydraulic equipment of the unit. In case of any works where it is not necessary that the unit is in operation, the apparatus has to be switched off by the control switch and the media connections have to be blocked.

In case of some works, mainly at the electrical part of the unit it is necessary to put the apparatus main switch to **Off**- position and to activate the main switch. It must be secured that the main switch cannot be switched on again, e.g. by means of a padlock, a safety notice. If necessary, remove fuses on site and store them in a safe place.

The observance of the maintenance intervals must be guaranteed by the operator. See chapter 16.4.4- Maintenance every six months by service technician.

3.3. Safety hints for operators / operating personal

3.3.1 Operation of the unit

Each working method, influencing the sterilization safety of the cycle, has to be omitted. The goods to be sterilized must be suitable for treatment in the unit in view of their size and materials. The authorized operator has to take care that no unauthorized persons are working on the unit (58946-6 – 04-2002 – 6.4).

The operator is obliged to check at least one time per charge whether any damages can be seen on the outside of the unit. He has to make immediate notice of any changes which may influence the safety (e.g. change in noise or time).

The operating company has to take care that the unit is only used in faultless condition. Principally no safety devices may be dismounted or set out of operation, as otherwise persons and things may be injured by temperature (e.g. steam) or other operating material (e.g. current, door).

The user of the unit has to take care that the operating instructions are kept directly at the unit together with the sterilizer book and that it is accessible for everyone and at any time.

The inspection chamber has to be closed always during normal operation and the key must be taken off and stored at a safe place.

The ventilation slits on the upper side of the apparatus may not be covered. Otherwise there is the danger that electrical and electronical parts are overheated and the function of the unit is negatively affected.

3.3.2 Operating means

In case of improper handling with electric current there is danger to life !

3.3.3 Closing of the door

The operator of the door must ascertain always that when closing the door there are no living beings and/or objects and solution which should not be sterilized.

3.3.4 Standstill

In case of longer standstill of the unit (e.g. over night) we recommend to block the media lines (water, feed water) by the local manual valves and to switch off the apparatus at the main switch.

Before switching on resp. resetting the unit into operation, the media lines (water, feed water) have to be opened again.

3.3.5 Medical Products Book

The Medical Products' book is part of the apparatus file. The following events must be written in the book:

Installation Control
Acceptance and commissioning
Judgement of power
Training (incl. the repetitions)
Routine checks – maintenance works (daily, weekly, monthly, every six months)
Inspections
Maintenance works
Repair works
Modifications at the sterilizer or the supply of operation means
Recommissioning
New judgement of power
Repeated check of the pressure vessel and its equipment
Extraordinary operation

3.4. Safety Hints (specific for the unit)

3.4.1 Heat

It cannot be avoided that the apparatus casing becomes hot during operation. The chamber door is a special heat store. Avoid each direct contact with the chamber door during operation. Take into consideration that the chamber door looses the heat taken up during operation only slowly and thus is also hot after operation.

When opening the chamber door after a finished program cycle there is the danger that hot air escapes from the chamber.

3.4.2 Electric

Opening the electric switch cabinet is only allowed to technical staff. The operating personal is not allowed to enter the unit. The door of the electric switch cabinet must always be locked. The key must be withdrawn and kept at a safe place, which is only accessible for authorized persons.

3.4.3 Danger hint

When opening the electric switchboard or cabinet or touching electrical parts or lines of the unit there is the danger of a current stroke.

With inappropriate contact with electric current (electricity) there consists mortal danger.

3.4.4 Operation

The apparatus may only be operated acc. to the operating instructions. The sequence of the individual operating steps must be followed strictly.

Disturbances and their consequences, which have been caused by unauthorized treatment during operation of the unit, are the responsibility of the user (causer).

Operation of the unit has to be done in accordance with the operating instructions. In case of disturbance or damages caused by non-observance of the operating instructions (wrong operation) the manufacturer does not undertake any responsibility.

The apparatus is constructed in a way that a wrong operation does not lead to a dangerous situation.

3.5. Operation means, Auxiliary materials

3.5.1 Gasket Grease

In order to guarantee the blocking resistance of the chamber door gasket, the recommended and offered grease from KSG should be used preferably.

3.5.2 Wear and tear parts and consumables

Chamber door gasket	Dipr 012 035
Gasket grease 50g	Fett 022 001
Gasket grease 100g	Fett 022 003
Gasket spray	Fett 022 005
Micro filter	Filu 023 005
Paper roll for printer	Schr 095 031
Colour ribbon for printer	Schr 095 015

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3.5.3 Feed water - Operation water

Feed water (Operation water) is the distilled, demineralized or completely desalted water in the feed water plumping and storage tank and generator used for the production of steam.

Only distilled, demineralized or completely desalted water may be used as feed water (Operation water). The conductivity of the operation way should not exceed 5 µs/cm.

Warning: Only distilled, desalted or demineralized water (feed water) may be used. Do not use tap water, as the calcarous sediments would attack and damage the stainless steel materials of the unit (chamber) and the heating elements of the generator. The cross sections of the pipings are reduced by these sediments, the magnetic valves cannot close orderly and the pressure and temperature sensors give false dates to the microprocessor command. Thus the unobjectionable operation of the unit is not guaranteed. A negative effect on the goods to be sterilized cannot be prevented, see chapter 20.1.3 - *series connection of two ion exchanger cartridges.*

The feed water is to be controlled daily. Among the control of the water quality the conductivity (15.6 Quality of feed water (operating water) and operating steam) must also be controlled. The recommended (DIN 58946-6:2002-04-8.2.2) value for the conductivity is ≤ 5 µS/cm (at 20°C). In order to control the feed water, it has to be taken out of the storage tank.

3.6. Accessories

3.6.1 Gasket drawer

The S-shaped gasket drawers serves for removing the chamber door gasket from the gasket groove for cleaning and maintenance works.

3.6.2 Special key

The special key serves for unlocking the bolts in the lid and the lateral casings.

3.6.3 Deposit plates

The two removable deposit plates in the chamber make it possible to use the chamber space optimally. Besides the use of a container 300 x 300 x 600 mm also smaller sterilizing containers and/or sieves resp. sterilizing goods welded in foil bags or hoses can be put into the chamber.

4. Construction and Function

4.1. Description of the function, operating and indicating elements

4.1.1 Instrumentation of the operating panel

Pressure gauge for boiler	Indicating pressure gauge for pressure in the boiler.
Pressure gauge for chamber	Indicating pressure gauge for pressure resp. low pressure in the sterilizing chamber.
Chamber thermometer	Indicating instrument for chamber temperature.

Operating part - Display.

Operating and indicating elements

Apparatus main switch with illumination.

Indicating instrument for conductivity of feed water (operating water). (Option)

Charge printer *

Water level glass	Indication of water level in the boiler

Reset button in case of water shortage.

* Upon demand of the user the charge printer can be omitted, if another cycle documentation in conformity with EN 285 is available.

4.1.2 Description of operating and indicating elements

Operating and indicating elements. These elements are built into the ergonomically shaped operating panel at the front side of the unit beyond the sterilizer door. The communication board consists of four resp. five constructional groups.

Indicating instrument of the boiler. The pressure gauge for the boiler is situated on the left side of the indicator board. Its graduation comprises a pressure range of -1 - +3 bar. The actual boiler pressure is indicated by the pointer of the indicating instrument.

Indicating instrument of the chamber pressure. This instrument is situated on the left side of the indicator board. Its graduation comprises a pressure range of -1 - +3 bar. The actual chamber pressure is indicated by the pointer of the indicating instrument. The pressure gauge for the chamber always shows the relative pressure. An indicated pressure of **0** bar corresponds to atmospheric pressure (approx. 1000 mbar).

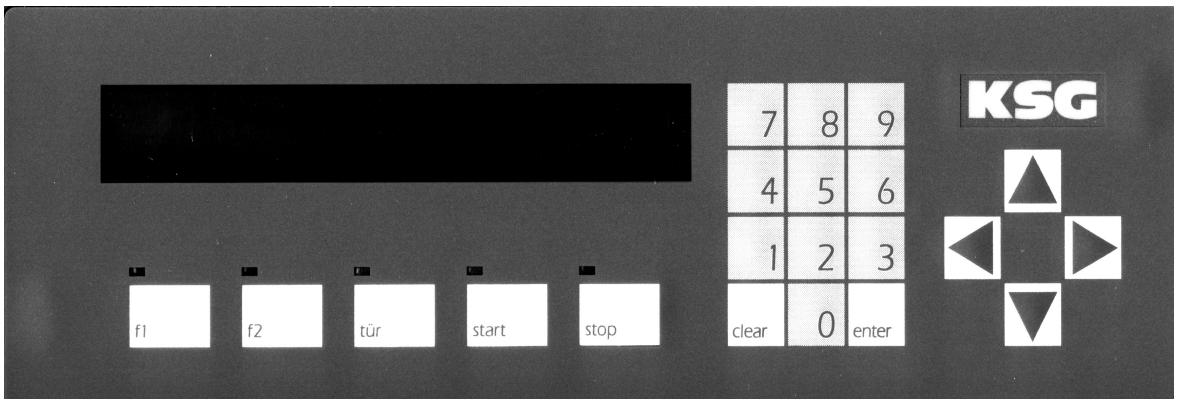
Indicating instrument for chamber temperature. This instrument is situated on the right side of the indicator board. Its graduation comprises a range of 0 - 160° C. The actual chamber temperature is indicated by the pointer of the indicating instrument.

Charge printer. If the unit is equipped with charge printer, the printer is situated on the right side of the indicato**r** board beyond the indicating instrument for the chamber pressure. The charge printer is controlled by the microprocessor command. (See operating and maintenance hints of the manufacturer of the printer).

Note: The a.m. side indications concerning pressure and temperature instruments as well as charge printer refer to the standard unit in right model (door folding on the left side, maintenance side on the right). In case of units in left model (door folding on the right, maintenance on the left) these constructional parts are arranged mirror-like.

4.1.3 Keyboard - Display

The operating/indicating module is situated between the indicating instruments for pressure and temperature. Due to its function (keyboard / display) it is an interactive part and serves as interface (communicator) between operator and unit.



The operating and indicating module consists of four components: a two-line display with each 20 characters, a five-point button group below the display, a nine-point button group on the right side of the display and a four-point cursor field.

Display. In the **upper display line** information concerning the software version number, the selected resp. active program and the program number as well as concerning the pressure in the chamber and the steam are placed at the disposal of the user - acc. to the status of operation and the program step.

In the **lower display line** the operator has information's concerning the status of operation. During the running program the actual program step is indicated.

4.1.4 Function buttons

f1	Function button **f1** is not occupied.
f2	Function button **f2** serves for filling the boiler with the prepared water (feed water) out of the storage tank.
tür	If the unit is at a status where the chamber door can be opened, LED over the button **tür** (door) is illuminated. For opening the chamber press button **tür** (door), while simultaneously swivelling the door handle to the left and opening the door blade.
start	When the boiler operating pressure is reached and a program has been selected and confirmed, LED **start** is illuminated. It goes out when an automatic program is started after corresponding preparation by actuating button **start**.
stop	Actuation of button **stop** leads to a stop of the active program step. The micro processor command changes into program step Drying. Afterwards the chamber is ventilated, the gasket sucked back and the door released.
clear	Button **clear** serves for resetting error notes resp. for returning to the program selection mode.
enter	Program selection is ended by button **enter**.

The illuminated LED over the function buttons **f2**, **tür** (door), **start** indicates the active status of the corresponding button. After having pressed this button, the corresponding step is carried out.

The LED over the **stop** button is illuminated after each program end and when this button has been actuated during a running program.

4.1.5 Opening the chamber door

The chamber door can always only be unlocked and opened by pressing button **tür** (door), when the LED over button **tür** (door) is illuminated.

Exception: Despite illuminated LED over button tür (door) the chamber door cannot be unlocked after button clear has been actuated and the cursor in the upper line is blinking.

The cursor buttons serve for adjusting the menu (see section adjustment of time, date and records).

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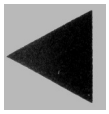

The cursor buttons serve for adjusting the menu (see section adjustment of time, date and records).

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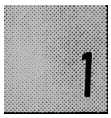
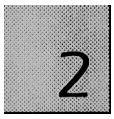
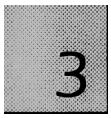
4.1.6 Program buttons



Selection button for program 1 **Standard**
Fractionated vacuum. Sterilizing temp. 134° C. Sterilizing time 4 minutes. Drying time 5 minutes.



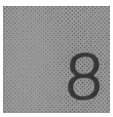
Selection button for program 2 **Special**
Fractionated vacuum. Sterilizing temp. 134° C. Sterilizing time 10 minutes. Drying time 15 minutes.



Selection button for program 3 **Thermolabile**
Fractionated vacuum. Sterilizing temp. 121° C. Sterilizing time 20 minutes. Drying time 15 minutes.

Selection button for program 4 **Vacuum test**
Pre vacuum. Waiting time 1 minute. Test time 10 min..

Selection button for program 5 **Bowie & Dick - test.**
Fractionated vacuum. Sterilizing temperature 134° C. Sterilizing time 3,5 min. Drying time 5 minutes.



Selection button for program 8 **Empty Sterilization.**
Fractionated vacuum. Sterilizing temperature 130° C - 134° C.
Sterilizing time 4 minutes. Drying time 5 minutes.

4.1.7 Actuation of the control panel buttons

In order to transfer the button impulses reliably to the microprocessor command, the buttons must always be pressed for one second.

4.2. Display- and Printer Configuration

4.2.1 Configuration of charge printer

The charge printer serves for recording the complete process course of one sterilization load.

The following process parameters are recorded:

Program name

Program step name

Start time of the individual program steps.

Sterilizing temperature

Pressure and low pressure

Number of program step repetitions

Date and time

Charge number

Acc. to **EN 285** (6.1.2.d / 6.3 - 6.3.3.2) in the edition of 19th April, 1996 sterilizers must be equipped with a registration unit.

The cycle documentation serves as control for the user and possibly against third parties as proof for a correctly executed sterilization.

Remark: Upon demand of the user, the charge printer can be omitted, if another cycle documentation in conformity with EN 285 is available.

4.2.2 Charge printer – Date and record adjustment

The adjustments for the charge printer and the display are made at the operating part. The adjustment level can only be reached from the ground level. Two different presentations of the ground level are possible.

The first presentation of the ground level is automatically reached after having switched the apparatus on and remains until the operating pressure in the boiler 2,4 bar) is reached.

Display: Program 1
Heating K/Door Time

The second presentation of the ground level is shown after having reached the operating pressure in the boiler (approx. 2,4 bar).

Display: Program 1
Open door Time

By pressing button ▼ the first window is opened.

Display: System Parameter *No modifications can be made here.*
Date Time

Pressing button ▼ the window showing the actual adjustment of the recording (printer switched on or off) is opened.

Display: Recording
On (Off)

Switch on or off the recording – switch on or off the charge printer.

For changing the adjustment button **enter** must be pressed. The presentation on the display is supplemented by a star in the upper display line. The star always shows the modification status.

Display: Recording *
On

By pressing button ◀ the recording adjustment changes from **On** to **Off.**

Display: Recording *
Off

By pressing button ▶ the recording adjustment changes from **Off** to **On**.

Display: Recording *
On

Pressing button **enter** confirms the selected condition. The star in the display disappears again.

Display: Recording
On

To reach the next adjustment level, button must be pressed again.

Display: Form
(short) **long**

Adjust the form of the print-out (short – long).

For changing the adjustment button **enter** must be pressed. The display is supplemented by a star in the upper display line. This stars always indicates that modification status.

Display: Form *****
long

By pressing button the recording adjustment changes from **long** to **short.**

Display: Form *****
short

By pressing button the recording adjustment changes from **short** to **long.**

Display: Form *****
long

Pressing button **enter** confirms the selected status. The star in the display disappears again.

Display: Form
On

In order to reach the next adjustment level, button ▼ must be pressed again.
Display: Adjust timer

Adjustment of date and time.

For changing the adjustment button **enter** must be pressed. The display is supplemented by a star in the upper display line and a cursor in the lower display line. The star always indicates the modification status.

Display: Adjust timer*
▮

By the numerous keys of the operating field date and time can be entered (see following example):

Button ▶ after entering one field serves as jump into the next entry field.

e.g. 12.09.99 14:53

1 2 ▶ 0 9 ▶ 9 9 ▶ 1 4 ▶ 5 3

Pressing button **enter** confirms the entry.
Display: Form
On

Pressing button ▼ leads to the level of the system parameters.
Display: System Parameter (No modifications can be made here).
Date Time

In order to leave the menu button ▲ must be pressed once.

In order to jump over the adjustments of the different levels button ▼ must always be pressed again.

5. Short operating instructions

Operating of the sterilizer acc. to the short operating instructions is only allowed to persons, who are familiar with the treatment of the sterilizer corresponding to section "Operating instructions". The short operating instructions shall only give a survey. It can in no case replace the operating instructions.

Cold water supply:	(Open cold water cock at site)
Main current supply:	(Switch on main switch at site)
Current supply for apparatus:	(Switch on main switch of the unit) (Heating-up phase of boiler water starts)
Fill storage tank until upper marking:	(Open water cock for feed water)
Upper marking of storage tank achieved:	(Close water cock for feed water)
Control water level of boiler and refill, if necessary:	(Press button **f2** continuously)
Open chamber door:	(Press button **tür** and swivel the door lever to the middle of the door)
Load chamber with goods to be sterilized:	If necessary
Close chamber door:	(Close door blade and swivel door lever into vertical position)
Operating steam pressure: bar)	(Wait until boiler pressure is approx.2,4
After appearing of note **Door open**/**Start**	(Actuate button **clear**)
Actuate the numeric button of the required program at the numeric block:	(Actuate button 1, 2, 3, 4, 5 or 8)
Confirm program selection	(by button **enter**)
Starting the program	(press button **start**)
The automatic program course of the selected program runs down.	
At the end of the program and after the sucking back of the gasket.	
Open door	(Actuate button **tür** (Door) and swivel the door lever to the middle)
Switching off the sterilizer:	
Current supply of apparatus:	(Close main switch of the unit)
Main current supply:	(Close main switch at site)
Cold water supply:	(Close cold water cock)

5.1. Programs

Program 1	**Standard**
Vacuum:	fractionated vacuum
Sterilizing temperature:	134° C
Sterilizing time:	04 minutes
Drying time:	05 minutes
Sterilizing goods:	solid **and** porous goods (instruments, textiles) also hollow bodies, in single and double packed (foil, paper textile or cassette etc.) form.

Program 2	**Special**
Vacuum:	fractionated vacuum
Sterilizing temperature:	134° C
Sterilizing time:	10 minutes
Drying time:	15 minutes
Sterilizing goods:	Difficultly to be aired, or to be dried, solid and porous goods (e.g., instruments, textiles, hoses) also hollow body (e.g., hoses), in repeatedly packed (foil, paper cloths or cassettes etc) form.

Program 3	**Thermolabile**
Vacuum:	fractionated vacuum
Sterilizing temperature:	121° C
Sterilizing time:	20 minutes
Drying time:	15 minutes
Sterilizing goods:	Temperature-sensitive (e.g., rubber, synthetic material, silicone), solid and porous goods, (e.g., instruments, textiles) also hollow body (e.g., hoses), in single and double packed (foil, paper cloths or cassettes etc.) form.

Program 4	**Vacuum Test**
Vacuum:	Pre vacuum
Equalizing time:	01 minute
Test time:	10 minutes
Sterilizing temperature:	125° C - 134° C
Sterilizing time:	05 minutes
Drying time:	05 minutes
Chamber condition:	Empty and dry chamber

Program 5	**Bowie & Dick - test**
Vacuum:	fractionated vacuum
Sterilizing temperature:	134° C
Sterilizing time:	3,5 minutes
Drying time:	05 minutes
Goods to be sterilized:	Bowie & Dick test utensils

Program 8	**Empty sterilization**
Vacuum:	fractionated vacuum
Sterilizing temperature	131° C - 134° C
Sterilizing time:	04 min.
Drying time:	05 min.
Chamber condition:	Chamber empty and dry.

6. Application Hints

6.1. Empty cycle / Bowie & Dick - test

To put the sterilizer into optimum operation conditions before the first charge of a day, an **empty sterilization** without loading the chamber has to be carried out acc. to DIN 58946-6:04-2002 / 6.4.2. For this empty sterilization you have to use automatic program **8** (empty sterilization with unloaded chamber).

After the empty cycle the **Bowie & Dick - test** (test program 5) must be carried out **daily** (DIN 58946-6:04-2002 / Table 1). The continuation of operation is depending on the result of the steam penetration test.

The Bowie & Dick-test as steam penetration test is a test system, the result of which gives a qualified evidence concerning the achievement of a sufficient air dilution in the chamber resp. in the test system after the fractionated vacuum process.

6.2. Sterilizing programs and goods to be sterilized

Sterilizing programs **P1** (Standard 134° C), **P2** (Special 134° C) and **P3** (Thermolabile 121° C) are identical in their course, however they are different in the sterilizing and drying times as well as in the sterilizing temperature. The parameters belonging to each program determine the use of the program resp. the goods to be sterilized and the method of packing.

6.2.1 Goods to be sterilized

In sterilizing program **P1** (**Standard 134° C**) solid and porous goods (also hollow body) may be sterilized in single and double packed (foil, paper cloths or cassettes etc) form with a sterilizing temperature of 134 °C.

In sterilizing program **P2** (**Special 134° C**) solid and porous goods (also hollow body) can be sterilized in repeatedly packed (foil, paper cloths or cassettes etc) form with a sterilizing temperature of 134 °C.

In sterilizing program **P3** (**Thermolabile 121° C**) solid and porous goods (also hollow body) can be sterilized in single and double packed (foil, paper cloths or cassettes etc) form with a sterilizing temperature of 121° C.

*(*e.g. the complete instrumentation made of stainless steels is belonging to *solid goods*).

All textiles belong to *porous goods.*

The temperature specific classification (**121° C or 134° C**) of the goods to be sterilized is always depending on the product qualification of the manufacturer. The corresponding indications concerning the max. permitted sterilizing temperature and time must be adhered to without any compromise. Moreover the permission statement of the manufacturer for sterilization in a steam sterilizer must be taken into consideration.

7. Setting into operation

7.1. Preparations – daily -

7.1.1 Control chamber door gasket.

Before switching the unit on, the chamber door gasket must be controlled and maintained daily. Please proceed acc. to the directions in chapter 15.1 *Maintenance of chamber gasket*.

Hint: The unlocking of the chamber door is only possible when the apparatus main switch is switched on and the LED over button **tür** (door) is illuminated. When the chamber door is closed, the apparatus main switch has to be switched on and the door to be unlocked. Afterwards the apparatus main switch has to be switched off again.

7.1.2 Cleaning of chamber.

Before switching the unit on the inner chamber and the inner side of the chamber door have to be cleaned daily and be freed from remainders, like adhesive tapes or similar. Please proceed as described in chapter 15.2 C*leaning and maintenance of chamber*.

7.1.3 Filling of storage tank:

After the cleaning works the filling level of the feed water (operating water) in the storage tank must be controlled. The storage tank is placed in the substructure cabinet of the unit. At its front side there is low (NW) and high water level (HW). In order to fill the storage tank, the red manual valve marked **Füllen** (filling) must be opened.

Control resp. open the local cold water main cock.

The manual valve is open when it is parallel to the pipe.
The manual valve is closed when it is in rectangular position to the pipe.

Observe the increasing level in the storage tank.

Close the manual valve again when the water level has reached the upper marking (HW) of the storage tank. Stay at the unit until the filling procedure is finished.

Warning: The filling procedure may not be executed without supervision.
- Danger of overflow-

When the apparatus is equipped with integrated ion exchanger system (option) you have to observe the pointer of the conductivity meter at the front side of the apparatus, see chapter 17.1 *Ion exchanger system.*

Important: Please take into consideration that only during the filling procedure the pointer instrument gives a real evidence of the conductivity of the feed water and the capacity of the cartridge.

7.1.4 Switching on the main switch at site:

Control resp. switch on the main switch at site.

7.1.5 Switching on the main switch of the apparatus:

Switch on the unit with the green main switch. (Lamp of the switch is illuminated). After having switched on the unit, always two routine windows are shown in the display.

Display: K S G
D-82223 Eichenau

Display: SW-Version (Software Versions number)
S/N: (Serial No. of unit)

After this program **1** is pre adjusted.

Display: Program 1
Heating boiler/Door Time

Hint: By switching on the main switch of the unit the boiler heating is automatically set into operation. It takes approx. 30 minutes until the operating pressure (2,4 bar) resp. the operating temperature (approx. 137° C) is reached. **The program can only be started when the operating pressure of the boiler has been reached.**

7.1.6 Control of boiler water level:

Control the boiler water level at the water level at the front side of the apparatus. Feed water may filled in max. to the upper marking of the water level glass.

7.1.7 Filling of boiler feed water:

The boiler water feeding process is executed by pressing button **f2** at the operating part. The function of the button is given when the LED over the button is illuminated. During the feeding process this button must be pressed continuously. The feeding process must be controlled at the water level glass.

Hint: Avoid a refilling of the boiler feed water during program steps **steam push, heating-up time** and **sterilization**.

Warning: Emptying of the storage tank below the NW marking must in any case be prevented, as when undergoing this marking there is the danger that the feeding pump draws air during the feeding process and interrupts the filling process. If this situation happens, the sterilizer must be switched off the first refilling must be executed with full storage tank and cold sterilizer.

8. Operation – Program course

Actuate button clear to select another program than the pre adjusted program 1.

Display: Program
Open door Time

Instead of **1** the cursor is blinking.

Select program: Actuate the corresponding numeric button (1-8) at the numeric block (e,g. **4** Vacuum test).

Display: Program 4
Open door Time

Confirm program selection: To confirm the selected program (e.g. 4 vacuum test), press button **enter**.

Program selection can only be confirmed if the heating-up phase of feed water (operating water) is finished, i.e. the operating pressure of approx. 2,4 bar is achieved (pressure gauge for boiler pressure).

Display: Vacuum test 134° C
Open door

Close/lock chamber door: Close the chamber door and lock it by moving the door handle circularly to the right until the limit stop into a vertical position.

Display: Vacuum test 134° C
Open door / Start

Starting the program:
By pressing button **start** the automatic program is set into operation.

The starting order is only executed when the chamber door is orderly closed and locked. Otherwise a corresponding error note is given (acoustic signal - display in the lower line changes between the texts "Open door" and "Door open"). To reset the error note, actuate button **clear**.

Hint: Before pressing button **start** the chamber door can be opened again by continuous pressing of button **tür** (door) and simultaneous moving of the door lever to the left.

8.1. Sterilizing program 1 Standard 134 ° C

Fractionated vacuum
Sterilizing time **4 minutes**
Drying time **5 minutes**

Before each program start control the water level in the boiler at the water level indicator and add feed water, if necessary.

By pressing button **start** the automatic program is set into operation.

Display:	..... mbar	... C	P 1
	Evacuation	1	00 min

In this program step the chamber is evacuated until 130 mbar.

Display:	0130 mbar	... C	P 1
	Evacuation	1	... min

Now program step "Steam push" follows:

Display:	0130 mbar	... C	P 1
	Steam push	1	00 min

After having opened the steam valve of the chamber the hot steam of the boiler is streaming into the chamber until there is an inner pressure of 1500 mbar.

Display:	1500 mbar	... C	P 1
	Steam push	1	... min

After the first steam push there is a steam reduction to 1200 mbar.

Display:	1200 mbar	... C	P 1
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the second program step "Evacuation" follows.

Display:	1200 mbar	... C	P 1
	Evacuation	2	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 1
	Evacuation	2	... min

steam is pushed in for the second time until 1500 mbar.

Display:	1500 mbar	... C	P 1
	Steam push	2	... min

After this second steam push, steam is reduced until 1200 mbar.

Display:	1200 mbar	... C	P 1
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the third program step "Evacuation" follows.

Display:	1200 mbar	... C	P 1
	Evacuation	3	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 1
	Evacuation	3	... min

the third steam push until 1500 mbar follows.

Display:	1500 mbar	... C	P 1
	Steam push	3	00 min

After the third steam push steam reduction until 1200 mbar takes place.

Display:	1200 mbar	... C	P 1
	Evacuation		00 min

After having reached 1200 mbar in the chamber, program step "Evacuation" takes place for the fourth time.

Display:	1200 mbar	... C	P 1
	Evacuation	4	00 min

When a pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 1
	Evacuation	4	... min

program step "Heating-up time" follows. By opening the steam valve for the chamber the hot steam is streaming from the boiler into the chamber. Chamber and goods to be sterilized are heated up to the corresponding sterilizing temperature.

Display:	0130 mbar	... C	P 1
	Heating-up time		00 min

After having reached the sterilizing temperature the corresponding sterilizing time runs down.

Display:	3250 mbar	*	134 C	P 1
	Sterilization			00 min

During program step “Sterilisation" the blinking star in the first display line and the counting of the time in the second display line shows the active condition of the time measurement.

Display:	3250 mbar	*	134 C	P 1
	Sterilization			04 min

When the sterilizing time is over, steam is led off the chamber until 1200 mbar.

Display:	1200 mbar	... C	P 1
	Steam reduction		00 min

Starting at 1200 mbar the vacuum pump sets in.

Display:	1200 mbar	... C	P 1
	Evacuation		00 min

When the chamber pressure has been reduced to 0700 mbar, program step "Drying" is started.

Display:	0700 mbar	... C	P 1
	Drying		00 min

This program step is maintained during the drying time belonging to the program.

Display:	.... mbar	... C	P 1
	Drying		05 min

After the drying time the chamber is ventilated and the gasket sucked back. Then you can open the chamber door and remove the sterile goods.

Open chamber door: Press button tür (door) continuously - LED over the button is illuminated – and move the door lever to the left in the horizontal position.

The program **standard 134° C** serves for the sterilisation of solid **and** porous goods, (e.g., instruments, textiles), in single and double packed (foil, paper cloths or cassettes etc) form. The application of the fractionated vacuum procedure in this program also allows the sterilisation of hollow bodies. The minimum sterilizing time prescribed with this temperature amounts to 3 minutes.

The temperature specific assignment of the sterilizing goods to a program specific temperature always depend on the product qualification of the manufacturer. Instructions of the manufacturer regarding the maximum allowed sterilizing temperature and – time has to be considered without compromise as well as restrictions of the mechanical stressability. The suitability for the steam sterilization should be confirmed by the manufacturer.

The maximum allowed loading of porous goods without packaging (e.g. textiles) to be sterilized in this chamber (220 x 220 x 450 mm / ca. 22 litre) volume is 3,5 kg.
The maximum allowed loading of solids (e.g. instruments) including containers and sieves to be sterilized in this chamber (220 x 220 x 450 mm / ca. 22 litre) volume is 3,5 kg.

The sterility of the sterilizing goods as a result from loading and program parameter is to be checked and to guarantee.

The sterilize effect of a loading in connection with the program, and with the program parameters must be guaranteed by a biological and thermoelectric test.

Solutions, independent from the size of the receptacles, may not be sterilized in this program.

Hint: Every program cycle must be finished with opening the camber door.

Hint: The data and values shown in the *program course* are standard indications which may deviate from the actual, optimized apparatus parameters.

8.2. Sterilizing program 2 Special 134 ° C

Fractionated vacuum
Sterilizing time **10 minutes**
Drying time **15 minutes**

Before each program start control the water level in the boiler at the water level glass and add feed water, if necessary.

By pressing button **start** the automatic program is set into operation.

Display:	..... mbar	... C	P 2
	Evacuation	1	00 min

In this program step the chamber is evacuated until 130 mbar.

Display:	0130 mbar	... C	P 2
	Evacuation	1	... min

Now program step "Steam push" follows:

Display:	0130 mbar	... C	P 2
	Steam push	1	00 min

After having opened the steam valve of the chamber the hot steam of the boiler is streaming into the chamber until there is an inner pressure of 1500 mbar.

Display:	1500 mbar	... C	P 2
	Steam push	1	... min

After the first steam push there is a steam reduction to 1200 mbar.

Display:	1200 mbar	... C	P 2
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the second program step "Evacuation" follows.

Display:	1200 mbar	... C	P 2
	Evacuation	2	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 2
	Evacuation	2	... min

steam is pushed in for the second time until 1500 mbar.

Display:	1500 mbar	... C	P 2
	Steam push	2	... min

After this second steam push, steam is reduced until 1200 mbar.

Display:	1200 mbar	... C	P 2
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the third program step "Evacuation" follows.

Display:	1200 mbar	... C	P 2
	Evacuation	3	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 2
	Evacuation	3	... min

the third steam push until 1500 mbar follows.

Display:	1500 mbar	... C	P 2
	Steam push	3	00 min

After the third steam push steam reduction until 1200 mbar takes place.

Display:	1200 mbar	... C	P 2
	Evacuation		00 min

After having reached 1200 mbar in the chamber, program step "Evacuation" takes place for the fourth time.

Display:	1200 mbar	... C	P 2
	Evacuation	4	00 min

When a pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 2
	Evacuation	4	... min

program step "Heating-up time" follows. By opening the steam valve of the chamber the hot steam is streaming from the boiler into the chamber. Chamber and goods to be sterilized are heated up to the corresponding sterilizing temperature.

Display:	0130 mbar	... C	P 2
	Heating-up time		00 min

After having reached the sterilizing temperature the corresponding sterilizing time runs down.

Display:	3250 mbar	*	134 C	P 2
	Sterilization			00 min

During program step “Sterilisation" the blinking star in the first display line and the counting of the time in the second display line shows the active condition of the time measurement.

Display:	3250 mbar	*	134 C	P 2
	Sterilization			10 min

When the sterilizing time is over, steam is led off the chamber until 1200 mbar.

Display:	1200 mbar	... C	P 2
	Steam reduction		00 min

Starting at 1200 mbar the vacuum pump sets in.

Display:	1200 mbar	... C	P 2
	Evacuation		00 min

When the chamber pressure has been reduced to 0700 mbar, program step "Drying" is started.

Display:	0700 mbar	... C	P 2
	Drying		00 min

This program step is maintained during the drying time belonging to the program.

Display:	.... mbar	... C	P 2
	Drying		15 min

After the drying time the chamber is ventilated and the gasket sucked back. Then you can open the chamber door and remove the sterile goods.

Open chamber door: Press button tür (door) continuously - LED over the button is illuminated – and move the door lever to the left in the horizontal position.

The program **special 134° C** serves for the sterilisation of solid **and** porous goods, (e.g., instruments, textiles), in single and double packed (foil, paper cloths or cassettes etc) form, which are to be aired **difficultly** and which are to be dried **difficultly**. The application of the fractionated vacuum procedure in this program also allows the sterilisation of hollow bodies. The minimum sterilizing time prescribed with this temperature amounts to 3 minutes.

The temperature specific assignment of the sterilizing goods to a program specific temperature always depend on the product qualification of the manufacturer. Instructions of the manufacturer regarding the maximum allowed sterilizing temperature and – time has to be considered without compromise as well as restrictions of the mechanical stressability. The suitability for the steam sterilization should be confirmed by the manufacturer.

The maximum allowed loading of porous goods without packaging (e.g. textiles) to be sterilized in this chamber (220 x 220 x 450 mm / ca. 22 litre) volume is 3,5 kg.

The maximum allowed loading of solids (e.g. instruments) including containers and sieves to be sterilized in this chamber (220 x 220 x 450 mm / ca. 22 litre) volume is 3,5 kg.

The sterility of the sterilizing goods as a result from loading and program parameter is to be checked and to guarantee.

The sterilize effect of a loading in connection with the program, and with the program parameters must be guaranteed by a biological and thermoelectric test.

Solutions, independent from the size of the receptacles, may not be sterilized in this program.

Hint: Every program cycle must be finished with opening the camber door.

Hint: The data and values shown in the *program course* are standard indications which may deviate from the actual, optimized apparatus parameters.

8.3. Sterilizing program 3 Thermolabile 121 ° C

Fractionated vacuum
Sterilizing time **20 minutes**
Drying time **15 minutes**

Before each program start control the water level in the boiler at the water level glass and add feed water, if necessary.

By pressing button **start** the automatic program is set into operation.

Display:	..... mbar	... C	P 3
	Evacuation	1	00 min

In this program step the chamber is evacuated until 130 mbar.

Display:	0130 mbar	... C	P 3
	Evacuation	1	... min

Now program step "Steam push" follows:

Display:	0130 mbar	... C	P 3
	Steam push	1	00 min

After having opened the steam valve of the chamber the hot steam of the boiler is streaming into the chamber until there is an inner pressure of 1500 mbar.

Display:	1500 mbar	... C	P 3
	Steam push	1	... min

After the first steam push there is a steam reduction to 1200 mbar.

Display:	1200 mbar	... C	P 3
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the second program step "Evacuation" follows.

Display:	1200 mbar	... C	P 3
	Evacuation	2	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 3
	Evacuation	2	... min

steam is pushed in for the second time until 1500 mbar.

Display:	1500 mbar	... C	P 3
	Steam push	2	... min

After this second steam push, steam is reduced until 1200 mbar.

Display:	1200 mbar	... C	P 3
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the third program step "Evacuation" follows.

Display:	1200 mbar	... C	P 3
	Evacuation	3	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 3
	Evacuation	3	... min

the third steam push until 1500 mbar follows.

Display:	1500 mbar	... C	P 3
	Steam push	3	00 min

After the third steam push steam reduction until 1200 mbar takes place.

Display:	1200 mbar	... C	P 3
	Evacuation		00 min

After having reached 1200 mbar in the chamber, program step "Evacuation" takes place for the fourth time.

Display:	1200 mbar	... C	P 3
	Evacuation	4	00 min

When a pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 3
	Evacuation	4	... min

program step "Heating-up time" follows. By opening the steam valve of the chamber the hot steam is streaming from the boiler into the chamber. Chamber and goods to be sterilized are heated up to the corresponding sterilizing temperature.

Display:	0130 mbar	... C	P 3
	Heating-up time		00 min

After having reached the sterilizing temperature the corresponding sterilizing time runs down.

Display:	2150 mbar	*	121 C	P 3
	Sterilization			00 min

During program step "Sterilization" the blinking star in the first display line and counting of the time in the second display line shows the active status of the time measurement.

Display:	2150 mbar	*	121 C	P 3
	Sterilization			20 min

When the sterilizing time is over, steam is led off the chamber until 1200 mbar.

Display:	1200 mbar	... C	P 3
	Steam reduction		00 min

Starting at 1200 mbar the vacuum pump sets in.

Display:	1200 mbar	... C	P 3
	Evacuation		00 min

When the chamber pressure has been reduced to 0700 mbar, program step "Drying" is started.

Display:	0700 mbar	... C	P 3
	Drying		00 min

This program step is maintained during the drying time belonging to the program.

Display:	.... mbar	... C	P 3
	Drying		15 min

After the drying time the chamber is ventilated and the gasket sucked back. Then you can open the chamber door and remove the sterile goods.

Open chamber door: Press button tür (door) continuously - LED over the button is illuminated – and move the door lever to the left in the horizontal position.

The automatism program **thermolabile 121° C** is suitable to the sterilisation of temperature-sensitive goods (e.g., rubber, synthetic material, silicone) in single and double packed (foil, paper cloths or cassettes etc) form, as well as to the sterilisation of solid and porous goods, (e.g., instruments, textiles) in single and double packed (foil, paper cloths or cassettes etc) form. To balance the lower sterilizing temperature, the sterilizing time is extended appropriately. The application of the fractionated vacuum procedure in this program also allows the sterilisation of hollow bodies. The minimum sterilizing time prescribed with this temperature amounts to 15 minutes.

The temperature specific assignment of the sterilizing goods to a program specific temperature always depend on the product qualification of the manufacturer. Instructions of the manufacturer regarding the maximum allowed sterilizing temperature and – time has to be considered without compromise as well as restrictions of the mechanical stressability. The suitability for the steam sterilization should be confirmed by the manufacturer.

The maximum allowed loading of porous goods without packaging (e.g. textiles) to be sterilized in this chamber (220 x 220 x 450 mm / ca. 22 litre) volume is 3,5 kg.

The maximum allowed loading of solids (e.g. instruments) including containers and sieves to be sterilized in this chamber (220 x 220 x 450 mm / ca. 22 litre) volume is 3,5 kg.

The sterility of the sterilizing goods as a result from loading and program parameter is to be checked and to guarantee.

The sterilize effect of a loading in connection with the program, and with the program parameters must be guaranteed by a biological and thermoelectric test.

Solutions, independent from the size of the receptacles, may not be sterilized in this program.

Hint: Every program cycle must be finished with opening the camber door.

Hint: The data and values shown in the *program course* are standard indications which may deviate from the actual, optimized apparatus parameters.

8.4. Test program 4 Vacuum test 125° C – 134° C

Pre vacuum	
Waiting time	**01 minutes**
Test time	**10 minutes**
Sterilizing time	**05 minutes**
Drying time	**05 minutes**

Before each program start control the water level in the boiler at the water level glass and add feed water, if necessary.

By pressing button **start** the automatic program is set into operation.

Display:	..... mbar	... C	P 4
	Evacuation	1	00 min

In this program step the chamber is evacuated until **130** mbar.

Display:	0130 mbar	... C	P 4
	Evacuation	1	... min

When this value is reached, an equalizing time of **one minute** takes place, after which the test phase of 10 minutes starts.

Display:	..... mbar	... C	P 4
	Waiting time		00 min

Display:	..... mbar	... C	P 4
	Test time		00 min

If the test is passed,

Display:	..... mbar	... C	P 4
	Test time		10 min

Program step "Heating-up time" follows. By opening the steam valve of the chamber the hot steam is streaming from the boiler into the chamber. Chamber and goods to be sterilized are heated up to the corresponding sterilizing temperature.

Display:	.... mbar	... C	P 4
	Heating-up time		00 min

After having reached the sterilizing temperature (125° C) the corresponding sterilizing time stars. During the sterilization period the temperature is increased to 134° C.

Display:	3250 mbar *	124° C	P 4
	Sterilization		05 min

During program step "Sterilization" the blinking star in the first display line and the counting of the time in the second display line show the active status of the time measurement.

When the sterilizing time is over, steam is led off the chamber until 1200 mbar.

Display:	1200 mbar	... C	P 4
	Steam reduction		00 min

Starting at 1200 mbar the vacuum pump sets in.

Display:	1200 mbar	... C	P 4
	Evacuation		00 min

When the chamber pressure has been reduced to 0700 mbar, program step "Drying" is started.

Display:	0700 mbar	... C	P 4
	Drying		00 min

This program step is maintained during the drying time belonging to the program.

Display:	.... mbar	... C	P 4
	Drying		05 min

After the drying time the chamber is ventilated and the gasket sucked back. Then you can open the chamber door and remove the sterile goods.

Open the chamber door: Press button **tür** (door) continuously - LED over the button is illuminated – and move the door lever to the left in the horizontal position.

8.4.1 Check upon vacuum tightness

Acc. to EN DIN 58 946-6, 12.14 the check upon vacuum tightness (vacuum test) has to be carried out monthly. After the daily maintenance and check works and the reaching of the generator operating pressure the vacuum test program should be carried out as first program of the day. After a successful test – as described in chapter 6 *Hints for Use* – an empty sterilization (Bowie & Dick test program without test system) and a Bowie & Dick - test have to carried out.

Before starting the vacuum test be sure that the chamber is empty, clean and dry.

Vacuum test failed

If the test phase is interrupted, because there is an inadmissibly high loss of pressure in the chamber, the chamber is ventilated and the door released for opening after the gasket has been sucked back.

Display: Vacuum test failed

The reasons for the failure of the vacuum test can be a leakage in the piping system, a dirty or defective door gasket or fat and water remainders in the chamber.

To be able to decide whether the sterilizer can be operated further, an empty sterilization (program **8** with empty chamber) has to be executed after the vacuum test. Afterwards the test program **5** (Bowie & Dick - test program) has to be executed.

If the judgement of the testing result is positive, the sterilizer can be operated, although the vacuum test has failed, as a successful process of the Bowie & Dick test proves a sufficient air dilution for the sterilizing process.

The vacuum test must be carried out again the next day. In order to achieve optimum conditions for the test, the following points must be checked resp. carried out carefully:

1. Chamber is empty, clean and dry.

2. The gasket has to be removed from the gasket groove, gasket groove and gasket have to be cleaned.

3. The gasket must be controlled on damages, then be greased and put back into the gasket groove.

If the vacuum test again is again interrupted during the test phase, you can proceed as described above (empty sterilization / Bowie & Dick - test). In case of positive result of the Bowie & Dick - test the sterilizer can again be operated further, as a sufficient air dilution could be proved by the successful course of the Bowie & Dick - test.

However, an authorized technician has to be informed in order to find out the reason for the repeated failure.

In case of negative result of the Bowie & Dick - test as control after a failed vacuum test, the sterilizer cannot be used further. A technician of local partner service has to be called at once to check and repair the unit.

8.5. Test program 5 Bowie & Dick - test 134 ° C

Fractionated vacuum
Sterilizing time **3,5 minutes**
Drying time **5,0 minutes**

Before each program start control the water level in the boiler at the water level glass and add feed water, if necessary.

By pressing button **start** the following program will run down:

Display:	..... mbar	... C	P 5
	Evacuation	1	00 min

In this program step the chamber is evacuated until 130 mbar.

Display:	0130 mbar	... C	P 5
	Evacuation	1	... min

Now program step "Steam push" follows:

Display:	0130 mbar	... C	P 5
	Steam push	1	00 min

After having opened the steam valve of the chamber the hot steam of the boiler is streaming into the chamber until there is an inner pressure of 1500 mbar.

Display:	1500 mbar	... C	P 5
	Steam push	1	... min

After the first steam push there is a steam reduction to 1200 mbar.

Display:	1200 mbar	... C	P 5
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the second program step "Evacuation" follows.

Display:	1200 mbar	... C	P 5
	Evacuation	2	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 5
	Evacuation	2	... min

steam is pushed in for the second time until 1500 mbar.

Display:	1500 mbar	... C	P 5
	Steam push	2	... min

After this second steam push, steam is reduced until 1200 mbar.

Display:	1200 mbar	... C	P 5
	Evacuation		... min

After having reached 1200 mbar in the chamber, the third program step "Evacuation" follows.

Display:	1200 mbar	... C	P 5
	Evacuation	3	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 5
	Evacuation	3	... min

the third steam push until 1500 mbar follows.

Display:	1500 mbar	... C	P 5
	Steam push	3	00 min

After the third steam push steam reduction until 1200 mbar takes place.

Display:	1200 mbar	... C	P 5
	Evacuation		00 min

After having reached 1200 mbar in the chamber, program step "Evacuation" takes place for the fourth time.

Display:	1200 mbar	... C	P 5
	Evacuation	4	00 min

When a pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 5
	Evacuation	4	... min

program step "Heating-up time" follows. By opening the steam valve of the chamber the hot steam is streaming from the boiler into the chamber. Chamber and goods to be sterilized are heated up to the corresponding sterilizing temperature.

Display:	.... mbar	... C	P 5
	Heating-up time		00 min

After having reached the sterilizing temperature the corresponding sterilizing time runs down.

Display: 3250 mbar * 134° C P 5
Sterilization 00 min

During program step "Sterilization" the blinking star in the first display line and the counting of the time in the second display line show the active status of the time measurement.

Display: 3250 mbar * 134° C P 5
Sterilization 3,5 min

When the sterilizing time is over, steam is led off the chamber until 1200 mbar.

Display: 1200 mbar ... C P 5
Steam reduction 00 min

Starting at 1200 mbar the vacuum pump sets in.

Display: 1200 mbar ... C P 5
Evacuation 00 min

When the chamber pressure has been reduced to 0700 mbar, program step "Drying" is started.

Display: 0700 mbar ... C P 5
Drying 00 min

This program step is maintained during the drying time belonging to the program.

Display: .... mbar ... C P 5
Drying 05 min

After the drying time the chamber is ventilated and the gasket sucked back. Then you can open the chamber door and remove the sterile goods. The further operation of the sterilizer depends on the judgement of the test result.

Opening of chamber door: Press button **tür** (door) continuously (LED over the button illuminated) and move the door lever to the left in the horizontal position.

The steam penetration test (Bowie & Dick - test) has to be executed **daily** after the empty cycle. as the further operation of the unit depends from the result of the steam penetration test. A Bowie & Dick - test has to be carried out always – also if vacuum test has failed – after the empty cycle, as its result is decisive for the further operation of the sterilizer.

Please take into consideration that the steam penetration is no judgement concerning a successful sterilization, only concerning a sufficient air dilution factor.

More decisive than a Bowie & Dick - tests or a Bowie & Dick simulation test is the predicate of an approved TST-test, where the three most important process parameter are controlled:

T Time
S Sterilization
T Temperature

In the structure of its program the Bowie & Dick - test program corresponds to the prescriptions and thus is suitable for all test systems approved at the moment.

In case of a negative test result the sterilizer may not be used further.

8.6. Program 8 Empty sterilization 131 ° C - 134 ° C

Fractionated vacuum
Sterilizing time **4 minutes**
Drying time **5 minutes**

Before each program start control the water level in the boiler at the water level indicator and add feed water, if necessary.

By pressing button **start** the automatic program is set into operation.

Display:	..... mbar	... C	P 8
	Evacuation	1	00 min

In this program step the chamber is evacuated until 130 mbar.

Display:	0130 mbar	... C	P 8
	Evacuation	1	... min

Now program step "Steam push" follows:

Display:	0130 mbar	... C	P 8
	Steam push	1	00 min

After having opened the steam valve of the chamber the hot steam of the boiler is streaming into the chamber until there is an inner pressure of 1500 mbar.

Display:	1500 mbar	... C	P 8
	Steam push	1	... min

After the first steam push there is a steam reduction to 1200 mbar.

Display:	1200 mbar	... C	P 8
	Evacuation		00 min

After having reached 1200 mbar in the chamber, the second program step "Evacuation" follows.

Display:	1200 mbar	... C	P 8
	Evacuation	2	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 8
	Evacuation	2	... min

steam is pushed in for the second time until 1500 mbar.

Display:	1500 mbar	... C	P 8
	Steam push	2	00 min

After this second steam push, steam is reduced until 1200 mbar.

Display:	1200 mbar	... C	P 8
	Evacuation		... min

After having reached 1200 mbar in the chamber, the third program step "Evacuation" follows.

Display:	1200 mbar	... C	P 8
	Evacuation	3	00 min

When a chamber pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 8
	Evacuation	3	... min

the third steam push until 1500 mbar follows.

Display:	1500 mbar	... C	P 8
	Steam push	3	00 min

After the third steam push steam reduction until 1200 mbar takes place.

Display:	1200 mbar	... C	P 8
	Evacuation		00 min

After having reached 1200 mbar in the chamber, program step "Evacuation" takes place for the fourth time.

Display:	1200 mbar	... C	P 8
	Evacuation	4	00 min

When a pressure of 130 mbar is reached,

Display:	0130 mbar	... C	P 8
	Evacuation	4	... min

program step "Heating-up time" follows. By opening the steam valve of the chamber the hot steam is streaming from the boiler into the chamber. Chamber and goods to be sterilized are heated up to the corresponding sterilizing temperature.

Display:	0130 mbar	... C	P 8
	Heating-up time		00 min

After having reached the sterilizing temperature (131° C – 134° C) the corresponding sterilizing time runs down.

Display:	3000 mbar	*	131° C	P 8
	Sterilization			00 min

During program step "Sterilization" the blinking star in the first display line and the counting of the time in the second display line show the active status of the time measurement.

Display:	3250 mbar	*	134° C	P 8
	Sterilization			4 min

When the sterilizing time is over, steam is led off the chamber until 1200 mbar.

Display:	1200 mbar	... C	P 8
	Steam reduction		00 min

Starting at 1200 mbar the vacuum pump sets in.

Display:	1200 mbar	... C	P 8
	Evacuation		00 min

When the chamber pressure has been reduced to 0700 mbar, program step "Drying" is started.

Display:	0700 mbar	... C	P 8
	Drying		00 min

This program step is maintained during the drying time belonging to the program.

Display:	.... mbar	... C	P 8
	Drying		05 min

After the drying time the chamber is ventilated and the gasket sucked back. Then you can open the chamber door.

Opening of chamber door: Press button **tür** (door) continuously (LED over the button illuminated) and move the door lever to the left in the horizontal position.

Attention: Automatic program 8 **Empty sterilization** is **no** sterilizing program (working program). Each try to sterilize goods is inefficient.

9. Function Description

Large sterilizer **KSG FLASH-2** is operated with tense, streaming and air-free saturated steam acc. to the fractionated vacuum procedure.

The apparatus has an integrated, electrically heated steam generator (boiler), which is arranged around the sterilizing chamber.

As optional a demineralization system is available, which produces the feed water (operation water) necessary for the steam production in the boiler.

The pure water leaving the demineralization cartridge is stored temporarily in the storage tank situated in the substructure cabinet of the unit. Filling of the storage tank is done manually by opening the red manual valve marked with **Füllen** (filling). The local cold water main cock must be open.

Filling of the boiler with the feed water (operation water) from the storage tank is effected via the electric motor feeding pump by pressing button **f2** at the operating part. The unit must be switched on at the apparatus main switch and the local main switch.

After having switched on the unit, the feed water (operation water) in the boiler is heated up to the operating steam pressure (2,4 bar) resp. the operating temperature (approx. 137° C).

The actual operating and program parameters are indicated in the display.

The chamber must be loaded acc. to the program. Afterwards the chamber door blade must be closed and be locked with the door lever.

The following programs can be selected by pressing numerous buttons **1 - 8** and confirming with button **enter**:

Program 1	:	Standard	134° C
Program 2	:	Special	134° C
Program 3	:	Thermolabile	121° C
Program 4	:	Vacuum test	125° C - 134° C
Program 5	:	Bowie & Dick - test	134° C
Program 8	:	Empty sterilization	131° C - 134° C

By pressing button **start** the automatic program run is started.

9.1. Description of the available sterilizing cycles

The following program course is given in programs 1, 2, 3, 5 and 8:

a) Pressing out of chamber door gasket against the door blade by boiler steam pressure. Release of following step after having reached the minimum gasket pressure at the gasket pressure controller.

b) Via the electric motor vacuum pump the air is evacuated from the chamber and the goods to be sterilized resp. by the Bowie & Dick - test system (porous materials) until 130 mbar.

c) Afterwards saturated steam up to approx. 1500 mbar is led from the boiler into the chamber.

Program steps b) and c) are repeated alternatingly (fractionated vacuum).

d) Constant letting in of saturated steam from the boiler into the chamber until the sterilizing pressure is reached (heating-up time).

e) Oscillating letting in (steaming-in hysteresis) of saturated steam from the boiler into the chamber until the corresponding sterilizing temperature is reached (heating-up time).

f) Oscillating letting in (steaming-in hysteresis) of saturated steam from the boiler into the chamber for maintaining the sterilizing temperature during the sterilizing time (Sterilization).

g) Pressure reduction in the chamber until approx. 1000 mbar via the condensate cooler.

h) Switching on the electric motor vacuum pump for producing the drying vacuum.

i) Start of the drying time when reaching approx. 700 mbar low pressure in the chamber (drying).

j) Equalization of the low pressure in the chamber to approx. 1000 mbar (Ventilation) and monitoring by chamber pressure controllers.

k) Sucking back of the gasket by the low pressure in the chamber tightening system produced by the vacuum pump and monitoring by the gasket pressure controller.

l) The release of the safety door magnet is indicated by the LED in button **tür**.

m) Unlocking of the door lever by pressing button **tür** and simultaneous swivelling of the door lever to the middle of the door.

n) Pushing open of chamber door blade with door lever.

o) Removal of sterile goods.

After the start of the program the program course cannot be interrupted. A stopping of the program course is at any time possible by pressing button **stop**.

By pressing button **stop** during the heating-up and sterilizing time (overpressure in the chamber) leads to emptying the chamber (steam reduction) and the changing-over to the drying phase. The drying process is effected for the time corresponding to the program. Afterwards the chamber is ventilated, the gasket sucked back and the door release indicated.

Pressing button **stop** during the vacuum phase (low pressure in the chamber) leads to changing-over to the drying phase. The drying process is effected for the time corresponding to the program. Afterwards the chamber is ventilated, the gasket sucked back and the door release indicated.

After a program stop the goods to be sterilized in the chamber must **always** be considered as **non-sterile** and must be sterilized again.

The following program course is given in program 4:

a) Pressing out of chamber door gasket against the door blade by boiler steam pressure. Release of following step after having reached the minimum gasket pressure at the gasket pressure controller.

b) Via the electric motor vacuum pump the air is evacuated from the chamber until 70 mbar (pre vacuum).

c) Switching off of vacuum pump and closing of all magnetic valves of the chamber system.

d) Waiting time of 1 minute before starting the vacuum test time.

e) Start of vacuum test time (10 minutes) and control of pressure loss in the chamber system.

f) When the test has been passed successfully, saturated steam is constantly let in from the boiler into the chamber until the sterilizing pressure is 134° C is reached (heating-up time).

g) Oscillating letting in (steaming-in hysteresis) of saturated steam from the boiler into the chamber until the sterilizing temperature of 125 – 134° C is reached (heating-up time).

h) Oscillating letting in (steaming-in hysteresis) of saturated steam from the boiler into the chamber for maintaining the sterilizing temperature during the sterilizing time (Sterilization).

i) Pressure reduction in the chamber until approx. 1200 mbar via the condensate cooler.

j) Switching on the electric motor vacuum pump for producing the drying vacuum.

k) Start of the drying time when reaching approx. 700 mbar low pressure in the chamber (drying).

l) Equalization of the low pressure in the chamber to approx. 1000 mbar (Ventilation) and monitoring by chamber pressure controllers.

m) Sucking back of the gasket by the low pressure in the chamber tightening system produced by the vacuum pump and monitoring by the gasket pressure controller.

n) The release of the safety door magnet is indicated by the LED in button **tür**.

o) Unlocking of the door lever by pressing button **tür** and simultaneous swivelling of the door lever to the middle of the door.

p) Pushing open of chamber door blade with door lever.

The failure of the vacuum test (pressure loss in inadmissible quantity) is documented by the print-out **test not passed**. The test phase is stopped. Afterwards the chamber is ventilated, the gasket sucked back and the door release indicated.

10. Working with the unit

10.1. General Remarks

Decisive for the necessary time for one cycle is the selection of the right program and the kind of the goods to be sterilized. Opposite to the basic times (sterilization - drying), which cannot be influence by the operator, the time can be influenced by a tight or loose packing method of the goods to be sterilized (textiles) and the used sterilizing container.

Thus the operator can shorten the cycle time by packing the textiles not to tightly in connection with a suitable sterilization container, as the time necessary for the fractionated vacuum is reduced.

Also the result of the drying procedure can be influenced by the operator by using the suitable sterilizing container and packing the goods correctly.

It is essential that the operator selects the influenceable factors in a way that the sterility of the goods to be sterilized is guaranteed.

10.2. Cleaning-, Packing- and Loading Hints

10.2.1 Cleaning of the goods to be sterilized before sterilization

Acc. to the requirements to a correct preparation in the sense of the prescriptions for sterile goods it is absolutely necessary that the goods to be sterilized are cleaned thoroughly before packing them. The cleaning of the goods (instruments, glass receptacles, syringes, hoses etc.) is necessary to avoid that albuminous and oily decontaminations are burning into the instruments or into the surface of the chamber.

A sufficient cleaning effect is possible when the instruments are soaked in a cleaning solution (water with fat- and albuminous-dissolving means) for at least 30 minutes.

Afterwards the instruments have to be rinsed intensively and to be cleaned again manually, if necessary. Special care has to be taken wash-active substances are removed.

The last rinsing process must be made by using completely desalted or distilled water. This procedure must be effected for solid and porous goods.

A manual drying of the instruments is absolutely necessary. It is recommended to prevent the use of oils. If the manufacturer of the instruments urgently recommends a treatment with oil, only emulging special oils for instruments may be used. Only few oil should be used.

Thermically dried (tumbler) or hot-ironed textiles must be cooled down at room temperature in unpacked condition.

10.2.2 Packing of goods to be sterilized

For individual packing of the instruments bags made of sterilization paper acc. to DIN 58 953, part 3 or a transparent packing (foil or paper) acc. to DIN 58 953, part 4 has to be used.

The sealing seams should have a width of at least 6 mm, double seams are recommended. Between the seam and the goods to be sterilized there should at least be a space of 30 cm. As alternative packing material sheets made of *non-woven* -material (no textiles) may be used.

Attention: Foil bags or hoses are not suitable as packing and should in any case be avoided. They can, however, be used as storage packing after sterilization.

Attention: Mull and/or cellulose bases in cassettes and sieve trays are not suitable.

Hint: Bowls and cassettes made of plastics should not be used because of their bad drying behaviour. Sterilizing containers made of aluminium have the ideal conditions for the sterilizing resp. drying process, however they are not offered very often because of the high production expenditure. Therefore we recommend to use sterilizing containers made of stainless steel. An adaptation of the necessary sterilizing and drying time to the used sterilizing containers and their loading is done corresponding to DIN 589 46, part 6, 13 validation.

The instructions of the manufacturer of the sterilizing containers has to be taken into consideration, especially concerning the points *cleaning* of the containers and *use* and *exchange* of filters.

Storage of the sterile goods has to be effected acc. to DIN 58 952, part 1.

DIN-page 58 946, part 5 is valid for the suitability of packing for goods to be sterilized.
KSG FLASH-2-E fulfils the highest requirement class acc. to EURO regulation FRW.

FRVV = **FR**ACTIONATED **V**ACUUM PROCEDURE

10.2.3 Loading Prescriptions

Sterilizer type KSG FLASH - 2 was manufactured acc. to DIN 58946.

When selecting the program care has to be taken that the selected sterilizing program is suitable for the goods to be sterilized and that there is no danger for the operating personal (e.g. easily inflammable textiles or aggressive materials).

The goods to be sterilized have to be cleaned, disinfected and dried before sterilization acc. to BGA regulation (regulation for understanding, prevention of and fight against infections in hospitals).

The packing of the goods must correspond to the sterilizing procedure (see DIN 58946, part 6, table 1).

After having loaded the sterilizing chamber, the door should be closed and the program be selected and started immediately. After the end of the program, the sterile goods should be removed at once. Due to this quick passage it is prevented that the goods to be sterilized before the sterilization and the sterile goods after the sterilization can be heated up inadmissibly high by the heated-up chamber jacket (**Attention: *Dry Heat***).

The doors of the empty sterilizing chamber between two cycles should always be closed to avoid a cooling down of the chamber and an unnecessary heat radiation.

10.3. Periodical test

In the curse of NA-MED (medical standard committee) it is the responsibility of the user to carry out the necessary function controls (biological and thermoelectric tests) corresponding DIN 58946-6:04-2002.

10.3.1 Steam penetration test

The steam penetration test (Bowie & Dick - test program **with** test system) has to be carried out **daily** after the empty cycle (Bowie & Dick - test program **without** test system), acc. to DIN 58946-6:04-2002, Table 1, 8.2.5 resp. the directions of the test manufacturer. The further operation of the unit is depending on the result of the steam penetration test. A Bowie & Dick test must always be effected after the empty cycle, also if the vacuum test has failed.

Please take into consideration that the steam penetration test makes no evidence concerning successful sterilization, but only concerning a sufficient air dilution factor of the unit. Thus it cannot replace suitable sterilization and spore tests. The sterilization efficiency of the sterilizer is depending on the result of the biological and thermoelectric test.

***Note**:* The use of alternative test systems acc. to E DIN EN 867-4 is permitted.

10.3.2 Vacuum test

Acc. to DIN 58946-6:04-2000, Table 1 *–test programs, table 1: survey about kind and time of the tests.* The test upon vacuum tightness (Vacuum test) has to be executed once a months acc. to *chapter 12 individual tests, point 12.1.4 – test upon vacuum tightness*. See chapter 6 *User hints* and 8.4 *Test program 4 Vacuum test 125 °C – 134 °C.*

11. Assisting hints for the use of the sterilizer

11.1. Program steps

Ventilation: During this program step the low pressure in the chamber produced during the drying process is reduced via the ventilation filter. The chamber is ventilated to atmospheric pressure (approx. 1000 mbar).

Steam reduction: During program step "Steam reduction" - following program step "Sterilization" - steam is let off by opening a corresponding magnetic valve until 1200 mbar are reached.

Steam push: Program step "Steam push" follows program step "Evacuation". Steam is streaming out of the boiler into the chamber until an inner chamber pressure of 1500 mbar is reached.

Sucking back of gasket: Program step "Sucking back of gasket" is the last active program step of the program cycle. By the vacuum pump an low pressure is produced in the piping system of the door gasket, due to which the gasket is sucked back into the gasket groove. Thus the door blade is released and the opening process can be executed.

Evacuation: During program step "Evacuation" an low pressure is produced in the chamber by the vacuum pump. The value of the low pressure is pre adjusted in the software program.

Heating-up time: The "Heating-up time" comprises the time between program steps "Evacuation" and "Sterilization", in which the chamber is heated up to the sterilizing temperature.

Sterilization: During program step "Sterilization" the corresponding time with the pre adjusted temperature and pressure runs.

Test time: This is the time (10 minutes) following program step "Equalizing time" in the vacuum test program. During the test time an eventual pressure loss in the chamber is noted by the microprocessor command via a pressure transformer. The further operation of the unit is depending on the results of this test.

Drying: Program step "Drying" is time-controlled, the individual time depends on the program and is regulated by the microprocessor command. During the drying phase the vacuum pump produces an under-pressure in the chamber, which together with the heat of the boiler dries the sterile goods.

Vacuum Holding Time. The equalization (waiting) time is the time in the vacuum test program which passes after having reached the given low pressure value for the chamber (70 mbar) until the start of the test time.

11.2. Error notes / Disturbances / Removal of disturbances

All parameters relating to the program are constantly controlled by the command system (Command electronics, pressure controllers, pressure regulators and temperature sensors).

In case of deviations, acoustical (buzzer) and optical (display) errors notes are indicated resp. printed out by the charge printer.

The acoustic signal sounds for one minute, it can be stopped by pressing button **clear**. The display alternatingly shows the text of the error note and the actual program step.

All disturbances indicating a **B** before the error text can be controlled and removed by the operating personal of the apparatus.

All disturbances indicating a **T** before the error text may only be controlled and removed by service technicians of the manufacturer resp. authorized service partners.

In case of disturbances, inform the works manager or the head of the department resp. the technical service.

For contacting the service department of KSG, kindly address to phone No. ++8142-29 57-0 or your responsible service technician.

First measures:

In case of steam exhaust at the apparatus the sterilizer must be switched off (actuate apparatus main switch).

If water is running out of the unit, the local cold water main cock must be closed.

Warning: If a program is interrupted or stopped by an error note, the goods to be sterilized must be considered as **unsterile**.

	Reasons:	Control:
Pressure gasket missing The pressure for pressing the door gasket against the door blade is missing, the chamber is not tightened. The program is not started resp. it is stopped and only continued after removal of the disturbance.	Overheat protection device has reacted Defile of steam supply in the boiler Defect of the magnetic valve steam gasket Defect of the command	**B**- Control the water level **B**- Check boiler pressure **T**- Control the LED at the magnetic valve plug **T**- Control / exchange the command
Pressure gasket available Wrong condition before opening the chamber door at the end of the program. The door gasket pressure has not been relieved, the door is not released for the opening movement.	- **Defect of the magnetic valve** Sucking back of gasket Defect of the pressure controller Defect of the command	**T**- Control the LED at the magnetic valve plug **T**- Control / exchange the pressure controller **T**- Control / exchange the command
Pressure sensor Disturbance of pressure transformer of the chamber, „data“ supplied to the electronics are not correct. The program is stopped and the door cannot be opened.	Defect of the pressure sensor Defect of the command	**B**- Determine the pressure by the pressure gauge **T**- Control / exchange the pressure sensor **T**- Control / exchange the command

	Reasons:	Control:
Pressure controller Pressure controller does not switch over to the pressure condition in the chamber, the door cannot be opened. The display alternatingly shows the error note *Pressure chamber – empty chamber*	Defect of one pressure controller	**B**- Determine the pressure by the pressure gauge **T**- Replace the one pressure controller
	Defect of Relay	**T**- Control / exchange the Relay
	Defect of the command	**T**- Control / exchange the command
Wrong program number The entered number for program selection (e.g. "0") is not stored as program number in the software	Program selection wrong	**B**- Correct program selection
Disturbance motor vacuum Motor protection switch for the vacuum pump has reacted in order to protect the motor from destruction in case of overload	Disturbance in the electric circuit (one outer conductor is missing or was missing for a short time during operation of the pump)	**T**- Control motor protection switch
	Motor protection switch defective	**T**- Exchange motor protection switch
	Vacuum pump defective	**T-** Control / exchange the vacuum pump

	Reasons:	Control:
Disturbance motor filling Motor protection switch for the feeding pump has reacted in order to protect the motor from destruction in case of overload	Disturbance in the electric circuit (one outer conductor is missing or was missing for a short time during operation of the pump) Motor protection switch defective Feeding pump defective	**T**- Control motor protection switch **T**- Exchange motor protection switch **T-** Control / exchange the feeding pump
Temperature sensor defective The „data“ sent by PT100 sensor to the electronics are higher resp. lower than the permitted value. Short-circuit resp. interruption in the PT 100 sensor.	PT 100 sensor defective Defect of the command	**T**- Control / exchange the sensor **T**- Control / exchange the command
Test not passed During the vacuum test time of 10 minutes an inadmissibly high loss of vacuum value has been measured in the chamber	Leakiness in the door gasket system Leakiness in the chamber system	**B**- Control / exchange the door gasket **T**- Control the chamber system
Door open If button **start** is pressed when the chamber door is not closed correctly (LED beyond the button is illuminated), error note *door open* appears in the display	Door lever not correctly closed Limit switch door closure defective	**B**- Close the door lever **T**- Control / exchange the limit switch

	Reasons:	Control:
Time out Time overrun during program step Evacuation	**Evacuation** Leakiness in the door tightening system Leakiness in the chamber system Defect of magnetic valve evacuation Cold water supply for the vacuum pump missing Deficiency of the vacuum pump Overload of goods to be sterilized Defect of the vacuum pump Defect of the command	 **B**- Control / exchange the door gasket **T**- Control chamber system **B**- Control the LED at the magnetic valve plug **B**- Control the cold water cock on site **T**- Control the blow and/or needle valve **B**- Check the load **T**- Control the vacuum pump **T**- Control / exchange the command
Time out Time overrun during program step Heating-up time.	**Heating-up time** Steam loss due to Leakiness of the chamber gasket Defect of the magnetic valve steam chamber Defile in steam supply in the boiler Defect of command	 **B-** Control / exchange the door gasket **T**- Control the LED at the magnetic valve plug **B-** Control boiler pressure **T**- Control / exchange the command

	Reasons:	Control:
Time out Time overrun during program step *Sterilization*.	**Sterilization** Steam loss due to Leakiness of the chamber gasket supply shortfall in steam supply in the boiler Defect of magnetic valve steam chamber Defect of the command	 **B**- Control / exchange the door gasket **B**- Control boiler pressure **T**- Control the LED at the magnetic valve plug **T**- Control / exchange the command
Time out Time overrun during program step *Ventilation.*	**Ventilation** Defect of magnetic valve Ventilation Ventilation filter obstructed Defect of the command	 **T**- Control the LED at the magnetic valve plug **T**- Renew ventilation filter **T**- Control / exchange the command
Overheating For protection of the boiler heating elements the overheat protection device has interrupted the heating circuit.	Water level in the boiler has sunk below the min. marking Defect of the Relay **Defect of the overheating** protection switch	**B**- Control water level in the boiler and add water, if necessary Reset overheat protection device **T**- Control / exchange the Relay **T**- Control / exchange the overheating protection switch

11.2.1 Water shortage

Water shortage in the boiler is indicated by text "Overheat" alternating with the display of the actual program step in the lower display line. The optical information is accompanied by an acoustic signal, which automatically stops after one minute. In case of water shortage in the boiler the heating elements are switched off. The program command stops the actual program step and changes over to the drying step.

Especially the acoustic signal draws the attention of the operating personal to an error of the unit. Thus it is possible to act quickly after reaction of the overheat protection device (error note)by actuating button **f2** (filling of boiler), unlocking the mechanics of the overheat protection device (press button below the main switch) and acknowledging the error note (pressing button **clear**), so that heating is switched on again, before the pressure of the boiler is going below the required value.

If the water shortage is not removed in time, i.e. if the pressure of the boiler is going below the value adjusted for the door gasket, error note "Overheat" is replaced by error note "pressure gasket missing", which is also accompanied by an acoustic signal for one minute. The command interrupts the actual program step and changes over to program step "Drying". Afterwards the gasket is drawn back the door is released.

11.2.2 Overheat protection device

The **overheat protection device** protects the boiler heating elements from destruction in case of water shortage. When the water shortage situation in the boiler has been removed (press button **f2** continuously and observe the green ball in the water level glass during the filling process), unlock the mechanism of the overheat protection device by pressing in the button below the apparatus main switch (if necessary, unscrew the cap before). When the mechanics has snapped in, the error note must be confirmed by button **clear**. Then the boiler heating again produces the operating pressure of approx. 2,4 bar. Standard program **1** appears in the display. The required program must be selected, confirmed and started.

11.3. Manual reduction of chamber pressure

The emptying of the overpressure in the chamber after a disturbance needs an especially responsible proceeding. The reason for the disturbance may be a temporary power failure or the switching off of the during the pressure phase (steam push, heating-up time and sterilization). The display alternatingly shows the error notes *pressure chamber – empty chamber* and *gasket pressure available*. The pointer of the chamber pressure gauge shows an overpressure in the chamber.

Before executing a manual emptying process, the apparatus must be switched off at the main switch for approx. 5 seconds. After having switched on again, numberous buttons 1 and 3 must be pressed ***simultaneously*** and ***continuously*** – observing the pointer of the chamber pressure gauge. By actuation of the numerous buttons an electromagnetic valve is opened, so that the chamber steam can escape into the drain. At a chamber pressure of approx. 1150 mbar (absolute pressure) the chamber door gasket becomes unstable and lets off the remaining pressure between chamber and chamber door. The developing noise as well as the pressurized steam (approx. 1150 mbar absolute pressure) are not dangerous.

Danger indication – Remaining risk:

There is the ***danger of burning*** from the escaping hot steam for the persons standing directly before the apparatus.

To avoid the danger of burnings, it is necessary to stand laterally from the chamber door during the manual emptying process. Furthermore it is recommendable to wear protective clothes (long-armed surgery coat or similar).

At the end of the emptying process the apparatus must again be switched off at the apparatus main switch for approx. 5 seconds and then be switched on again. After having switched on again the ventilation and gasket relief valve opens. When the LED beyond button **tür** is illuminated, the chamber door can be unlocked and opened by pressing the button. The goods to be sterilized must be considered as unsterile and be sterilized again.

Before starting the program again, the boiler operating pressure (approx. 2,4 bar) must be available. The program must be selected and confirmed again.

11.4. Automatic reduction of chamber pressure

After occurring of the a.m. situation, the chamber pressure can be reduced without any danger by switching off the unit at the apparatus main switch. When switching the unit off, also the heating elements are set out of operation and the steam production is stopped. Letting the unit cool down in switched off condition for approx. 2 1/2 hours, the pressure of the chamber as well as of the boiler falls down to zero. When the chamber is pressureless, the unit can be switched on again.

When switching the unit on again, the ventilation and gasket relief valve opens. When the LED beyond the button **tür** is illuminated, the chamber door can be unlocked and opened by pressing this button. The goods to be sterilized in the chamber must be considered as **unsterile** and be sterilized again.

Before starting the program again, the boiler operating pressure (approx. 2,4 bar) must be available. The program must be selected and confirmed again.

12. Constructional and technical devices

12.1. Chamber door

12.1.1 Swivel door

The **chamber door** is equipped with a safety closure. The closure bolt has two blocking wings at its ends. These can only be led through the closure loop of the apparatus when the door handle is in horizontal position. A contact switch inquiries the position of the blocking wings. By turning the door handle into vertical position the contact switch is actuated. Thus a blocking bolt locks the blocking wings in their position. Only in this condition it is possible to start a program.

Opening of the chamber door is only possible in ***pressureless*** condition. If this condition is given, LED over the button "door" is illuminated. If this button is actuated, the locking bolt of the electromagnet is unlocked and the door handle can be swivelled to the left for opening.

12.1.2 Door tightening

The steam- and vacuum-proof tightening between chamber and chamber door is effected by a blowable silicone special gasket, which is pressed against the door blade after the start of the program.

At the end of the program – provided that certain safety conditions are fulfilled (see section monitoring devices) – the gasket system is relieved and the silicone gasket is sucked back into the gasket groove by the low pressure produced by the vacuum pump. Thus the steam- and vacuum-proof tightening between chamber and door blade is repealed.

12.2. Vacuum pump

To avoid the transmission of bone conduction as far as possible and to fulfil the requirement of DIN 58946, part 2, point 5.3 – i.e. not to exceed a sound level of 68 dB (A) – the vacuum pump is placed on rubber feet.

Out of the same reason the pump must elastically be connected to the drain system by a hose of at least 400 mm.

13. Monitoring Devices

13.1. Overheat protection device

The **overheat protection device** protects the heating elements from destruction in case of water shortage. In case of a water shortage situation the boiler heating elements are switched off and the steam production is stopped. When the feed water (operating water) in the boiler has been added, the mechanism of the overheat protection switch can be reset.

13.2. Door gasket pressure

The **pressure on the door gasket** is controlled by a pressure controller. The boiler steam serves as pressure medium. If the gasket pressure should fall below the value adjusted at the pressure controller - due to an Leakiness in the gasket tube system or an interruption in the steam production - error note "Pressure gasket missing" appears in the display, accompanied by an acoustic signal, which stops automatically after one minute. The command interrupts the actual program step and changes to program step "Drying" for the corresponding drying time. Afterwards the gasket is sucked back and the door released.

13.3. Relief of chamber door gasket

13.3.1 Pressure

The chamber door tightening system may only be relieved resp. the opening movement of the closure door may only be released when the pressure in the chamber is < 0,1 bar. This is determined by two independently working pressure controllers, which are controlled by the inner pressure of the chamber. The pressure controllers control themselves, i.e. they are inquired whether they have changed their contact position during the pressure phase. If this is not the case, there must be a defect. The gasket is not relieved and the chamber door cannot be opened. Each further intervention at the unit must be omitted. For removal of the disturbance a technician authorized by KSG or the service department of KSG directly must be ordered.

13.4. Door limit switches

The door limit switches control the orderly closed condition of the chamber door. If the door is not correctly closed, the program cannot be started.

14. Safety Devices

14.1. Safety valve

If by failure of the pressure regulator the heating elements are not switched off, the **safety valve** prevents that an inadmissibly high pressure in the boiler is reached. From a pressure of more than 2,5 bar the safety valve opens and releases the way to the outside to lead off the steam safely. When the safety valve has reacted, the sterilizer has to be switched off by the ON/OFF switch and the apparatus has to be checked.

15. Maintenance, care and cleaning hints

15.1. Care of the door gasket

To guarantee a safe tightening between chamber and door to maintain the blocking resistance of the chamber gasket, the gasket must be removed from the gasket groove and cleaned **daily**. The maintenance intervals are not only depending on the frequency of use of the unit. As the gasket grease looses its separation abilities also when the unit is not used - only be its contact with air - the maintenance is in any case depending on the blocking resistance of the gasket.

The gasket should be cleaned when the unit is cold and not heated up. To protect the hands during the work with the gasket and the grease it is recommendable to use one-way rubber gloves.

The gasket is removed from the gasket groove by the gasket drawer when the camber door is open. It has to be cleaned with a fluff-free cloth and afterwards to be checked whether it is not damaged. A worn-out or damaged gasket must be replaced.

Afterwards the gasket groove must be cleaned. For greasing the gasket put a quantity of grease of approx. a walnut on one hand and rub it between your hands before pulling the gasket through your hands.

The greased gasket is then placed back into the gasket groove.

The blocking resistance of the door gasket must be checked daily when the sterilizer is still cold.

It is recommendable to have always a spare gasket, as a defective door gasket makes it impossible to operate the unit orderly and causes an unnecessary standstill.

15.2. Cleaning and care of the chamber

The durability and safety of the inner walls of the pressure vessel can be prolonged essentially when certain precautions are taken.

The surface of the inner chamber wall should always look metallically smooth. If the inner wall is covered with a grey or spotted layer, this should be removed by careful means (e.g. water with detergent addition or other rinsing solutions).

Do <u>in no case</u> use nitro, tri, per or acetone solutions !

Smallest spots of rust lead to pitting and after a short time to destruction of the pressure vessel. These spots have to be removed carefully by fine emery paper. **Do not use steel wool!** Afterwards the inside of the chamber must be cleaned.

The cleaning of the chamber has to be made every day before setting into operation, i.e. when the unit is still cold. It is very important that all things must be removed from the chamber, i.e. all sieve trays and inset rack. Besides the chamber also the sieve trays, the inset rack and the inner side of the door must be cleaned. Normally it is sufficient to clean the unit with a moist and fluff-free cloth.

Once a week the inner chamber has to be sprayed with a stainless steel detergent before switching off the unit. This spray should stay in the chamber over night. Before setting the unit into operation again, the chamber should be cleaned with a dry, fluff-free cloth and fluffs or other dirt particles should be removed.

During the daily operation the chamber has to be checked whether there a remainders of packing materials, adhesive strips or similar, which have to be removed before a new sterilization.

Do in no case use steel wool !

Do in no case use nitro, tri, per or acetone solutions !

15.3. Cleaning of the apparatus casing

The stainless steel casing and the type plates have to be cleaned once a week with silicone oil or a stainless steel caring agent and a smooth polishing cloth.

Special care has to be taken that no caring agent and/or spray is dropping through the ventilation slots of the apparatus lid to the electric switchboard situated thereunder.

To be able to clean the bottom of the substructure cabinet thoroughly, it is necessary to remove the ion exchanger cartridge and the storage tank.

15.4. Control of boiler water

At least once a week the boiler water has to be controlled on sediments. **This may only be done when the unit is cold and not heated up (boiler pressure gauge 0 bar) and the apparatus is switched off**.

In the substructure cabinet of the unit there is a red wing screw manual valve (water outlet manual valve for boiler water) with a hose of approx. 50 cm.

The hose end has to be led into a clean receptacle. By careful opening of the manual valve approx. 1 litre of boiler water has to be let off. The water should then be controlled on sediments. The water removal should be repeated until there are no or only few sediments.

The boiler water should be controlled monthly. The control should consist at least of the control of the conductivity (≤ 5 µS/cm at 20° C) and the determination of the concentration of the SiO_2. (DIN 58946-6: 04-2002-8.2.3).

15.5. Renewal of boiler water

Once a month the boiler water has to be let off completely. **This may only be done when the unit is cold and not heated up (boiler pressure gauge 0 bar) and the unit is switched of**.

For this reason, the hose end of the water outlet manual valve for boiler water has to be led into a corresponding receptacle (bucket) and the manual valve has to be opened carefully. Now the boiler water has to be let off completely. After having emptied the boiler water, the manual valve has to be closed completely.

Before refilling the housing lid must be removed acc. to chapter 18.5 *Setting into operation after installation* and the three automatic fuses (heating) marked F1 must be switched off. Only when the heating automatic fuses F1 are switched off the sterilizer may be switched on at the main switch and the boiler be filled by pressing button **f2**. The feeding process should be observed at the water level glass. An overfilling of the boiler with feed water (operating water) should in any case be prevented. After the filling process a rinsing process should be executed by letting off approx. 1-2 litres of feed water (operating water) for several times. Afterwards the sterilizer must be switched off at the main switch and the three automatic fuses F1 must be switched on again. When the housing lid is placed on again and locked, the unit can be switched on again at the apparatus main switch. Thus the heating-up of the boiler water to the operating temperature (approx. 137° C) is started.

***Danger**:* When touching *electrically conductive* elements there is danger to life !

Hint: As the micro heating element is active during the filling process, it is possible that the water shortage protection switch (overheat protection) reacts. This is indicated by an acoustic signal and the error note Overheat in the display. This acoustic signal automatically stops after 1 minute. By pressing button clear this signal can be ended prematurely. The reaction of the water shortage protection switch has no influence on the filling process. After the filling process the water shortage protection switch must be reset. This is done by pressing in the push-button underneath the apparatus main switch (if necessary remove the screw cap before). When the push-button has snapped in, the error note must be confirmed by pressing button clear.

15.6. Quality of feed water (operating water) and operating steam

Max. value for contamination in the steam

Contamination in the condensate and feeding water

	Condensate	Feeding water
Evaporation remainders	≤ 10 mg/kg	≤ 10 mg/l
Silicium oxide, SIO2	≤ 1 mg/kg	≤ 1 mg/l
Ferrous	≤ 0,1 mg/kg	≤ 0,2 mg/l
Cadmium	≤ 0,005 mg/kg	≤ 0,005 mg/l
Plumbous	≤ 0,05 mg/kg	≤ 0,05 mg/l
Heavy metal traces excl. ferrus, cadmium and plumbous	≤ 0,1 mg/kg	≤ 0,1 mg/l
Chloride (CL‘)	≤ 0,1 mg/kg	≤ 2 mg/l
Phosphat (P2O5)	≤ 0,1 mg/kg	≤ 0,5 mg/l
Conductivity (at 20°C)	≤ 3 µS/cm	≤ 5 µS/cm
ph-value (degree of acidity)	≤ 5 to 7	≤ 5 - 7
Hardness (∑ earth alkali iones)	≤ 0,02 mmol/l	≤ 0,02 mmol/l
Colour		colourless, clear without sediments

Non-condensable gases
Non-condensable gases dissolved in the feed water may cause an increase in non-condensable gases in the steam, see **prEN 285:2002/13.3.2.**

The steam produced from the feed water may not exceed non-condensable gases of 3,5 volumes % if he is measured after **prEN 285:2002 / 22/1.**

Note: The use of feeding water (operating water) or steam produced thereof (operating steam) with components beyond the a.m. values can essentially shorten the lifetime of the sterilizer and suspend the guarantee of the manufacturer completely or partially.

The value indications are made acc. to EN 285 / 1996.

15.7. Aeration Filter

Due to its construction the aeration filter guarantees a safe air filtration. Exchange of the filter elements is easily possible.

To guarantee the operation safety of the sterilizer and to prevent a recontamination of the goods to be sterilized, the service department must exchange the filter acc. to chapter 16.4.4.*Maintenance every six months by a service technician.*

The filter inset, however, has to be renewed when **6 months** have passed

Under consideration of the local circumstances, like dust and humidity, as well as in case of extremely frequent use, it might be necessary to renew the filter in correspondingly shorter intervals.

The exchange of the filter can be done by the user as follows:

Unlocking of the lateral casing (maintenance side) with a special key.
Take off the lateral casing to the top.

Pull out the aeration filter from the connection piece.

Write the actual date on the new aeration filter.

Clean both rubber rings with a wet cloth and press the filter with the wet rubber rings into the connection piece until the stop.

Put lateral casing on again and lock it.

Aeration filter: Article No. Filu 023 005

Concerning exchange of filter by the user please see chapter 16.4.4 *Maintenance every six months by a service technician.*

15.8. Decalcification of vacuum pump

The suction capacity of the vacuum pump results from the electromechanical turning movement of the pump motor resp. the pump mechanics, the supplied cold water quantity and the air volume sucked by the blow valve. The cold water quantity for the vacuum pump is adjusted by a manually regulated needle valve. The needle and the blow valve must be adjusted according to the conditions (water pressure) at site.

During the operation of the vacuum pump lime is continuously separated of the water streaming through the pump and covers the surface of the pump. The calcification of the mechanics of the vacuums leads to a reduction of the pump capacity and an increased current consumption of the motor.

The capacity reduction of the vacuum is mostly recognized in a prolongation of the vacuum and drying times. Moreover the noise of the pump during the operation is also changed.

To protect the electric motor of the vacuum pump from damages and destruction, a motor protection switch is integrated into the motor supply line. The switching off currency is adjusted corresponding to the nominal current of the motor. In case of an increase current consumption of the motor due to calcification the motor protection switch switches off automatically, i.e. it separates the motor from the current supply. The motor protection switch can be switched on again after cooling by pressing the black knob.

To avoid the above-described procedures due to a calcification of the vacuum pump and the stand still times of the unit after reaction of the motor protection switch, the vacuum pump has to be decalcified regularly.

The period between the decalcification procedures is determined by the lime contents of the water and the frequency of use of the unit.

Decalcification of the vacuum pump belongs to the maintenance works, in connection with a maintenance contract.

The vacuum pump should only be decalcified by a technician. If decalcification becomes necessary before maintenance work, the service technician must be called separately.

16. Maintenance and care

16.1. Maintenance

Take care that constructional parts which serve for the safety of the unit are checked and maintained regularly.

If defects or damages are found at the pressure vessel or the safety devices, the sterilizer has immediately to be set out of operation and the technical manager must be informed.

Out of reasons of operation safety, function safety and economy steam sterilizer should be checked once a year by an authorized person of the manufacturer or another expert.

16.2. Exchange of parts

In case of repairs the original spare parts indicated by the manufacturer or equivalent parts permitted by the manufacturer have to be used. Installation may only be carried out by an expert.

Repair works at limiting devices as well as other safety devices have to be executed by the manufacturer resp. by an authorized person.

After repair works an extraordinary examination concerning sterilizing efficiency has to be executed. The range of examination has to be determined by an expert.

The necessary examinations after repair works must be executed by the service technician acc. to the instructions (written test instruction).

16.3. Examination

The ***Recurrent Examination*** must be executed acc. to the valid directions for *steam boilers* and *pressure vessels*.

16.4. Maintenance directions for operating staff / service technicians

16.4.1 Daily maintenance and control by the operating staff

The daily maintenance and control works have to be carried out daily by the operating staff acc. to form *Maintenance and Control daily*.

16.4.2 Weekly maintenance by the operating staff

The weekly maintenance and control works have to be carried out by the operating staff acc. to the form *Maintenance and Control weekly.*

16.4.3 Monthly maintenance by the operating staff

The monthly maintenance and control works have to be carried out by the operating staff acc. to the form *Maintenance and Control monthly*.

16.4.4 Maintenance every six months by service technician

The maintenance and controls works every six months have to be carried out every six months by an authorized service technician acc. to form *Maintenance and Control six months*.

The control of the steam generator plant, especially the regulating, safety and warning devices, has to be executed by a skilled service technician when **6 months** have passed.

16.4.5 Basis for maintenance works

Basis for the maintenance and control works are the *maintenance and control records* and *the form page*.

17. Prerequisite conditions for the operation of the apparatus

17.1. Place of installation

The place of installation must be clean and dry. An ideal room temperature of 21° C should not be exceeded. There must be an optimum supply of fresh air.

The ground must be plain and horizontal.

The ground construction must be suitable for the weight of the apparatus (see installation drawing).

Under consideration of the local circumstances, the place of installation must be selected in a way that by the unavoidable noise of the vacuum pump during operation the surrounding rooms are only affected moderately.

The maintenance side of the unit must always be accessible. There may neither be mobile nor continuous devices blocking this side.

The maintenance room beyond the apparatus must be kept free until the ceiling, so that a ventilation of the upper side of the apparatus is guaranteed at any time. The apparatus lid must always be removable without problems.

The space before the apparatus must be dimensioned in a way that the operation of the apparatus and the loading and unloading of the chamber is always possible comfortably.

The local main switch and the local cold water cock for the apparatus must be marked clearly and be positioned at a place that it can be reached and activated at any time.

Warning: The operation room must be free from easily inflammable materials (by ignition of inflammable mixtures, gases or damps).

17.2. Mounting directions

For mounting and setting into operation, the following points have to be taken into consideration:

We recommend that mounting and setting into operation is done by our own experts or persons authorized by us. At least installation should be checked by experts before setting into operation.

This results in:

a) best conditions for a faultless setting into operation

b) unobjectionable basis for our guarantee works.

Before mounting - even better immediately after receipt of the unit at the place of installation - please check whether the consignment is complete.

If the sterilizer should be placed on a basement or a pedestal on site, please check all dimensions on the installation plan resp. on the unit.

The apparatus must be aligned by using a bubble level.

The apparatus has either to be placed on the pedestal prepared on site or on the delivered stainless steel pedestal with stainless steel tub. It has to be aligned by a bubble level.

Frame and pedestal have to be sealed by reasons of hygienics and tightness.

All media connections have to be provided with catch pans and stop manual valve. The sterilizer must be connected acc. to the installation plan and the locally valid directions.

Before connection all tubes have to be cleaned, so that contamination's as rust, splinters, insulation material or similar do not influence the function of the valves.

During mounting and setting into operation the following points must be adhered to:

The sterilizer must be connected acc. to the installation plan and the locally valid directions.

Moreover please check whether the voltage and current indicated on the type plate correspond to the local ones.

18. Hints for installation

18.1. Casing and security during transportation

If the apparatus is not transported by the manufacturer, the apparatus is placed into a wooden case. The apparatus must be transported or stored in upside-down or upright position. When removing the wooden casing, begin with the top plate. Afterwards the lateral walls can be dismounted in any sequence.

***Attention**:* Before installation the securing nuts of the vacuum pump must be removed.

18.2. Securing nuts for transportation

For removing the securing nuts the apparatus must be in upside-down position. The four nuts at the bottom can be unscrewed by a forked or box end wrench. The nuts must be screwed of completely.

18.3. Dismounting – Mounting of the casing sheets

After the apparatus has been brought into upright position, the lid and the casing sheet of the maintenance side must be removed. The lid can be lifted to the top after the lid lock has been unlocked by a special key. The maintenance side depends on the execution of the apparatus. The standard (left) execution has the chamber on the left side. Thus the maintenance side is on the right side. The right execution has the chamber on the right side. Thus the maintenance side is on the left side. The lateral casing of the maintenance side can be removed after the lock has been unlocked with the special key. A removal of the opposite lateral casing is not necessary.

The mounting of the lid and the lateral sheet of the maintenance side is done in opposite sequence.

18.4. Connection of operating means

For operation of the unit the electrical and cold water connections as well as the cooling water drain have to be prepared acc. to chapter 22 *Technical Information.*

18.4.1 Electrical connection

For reasons of safety and later maintenance works a locally installed main switch must be available before each apparatus. Moreover the apparatus must have a separate fault current protection switch.

The electric connection line between local main switch and the main binders of the apparatus (X1-L1,L2,L3,N,PE) should preferable by made with a flexible line. The diameter of the line must at least be 6 mm^2. As binders of terminal strip X1 *feather binders* of Messrs. Wago are used. The electric connection has to take place as a **right rotating field**. The **right rotation sense** of the vacuum pump and food pump is to be checked and to guarantee.

18.4.2 Cold water connection

The cold water connection has a 1/2" winding.
The cold water must have a constant pressure of 3-5 bar.

The connection between the local cold water cock (corner valve) and the apparatus should be made by a copper tube or a flexible armoured hose. When using a hose please make use that it can withstand continuously the local water pressure. It is recommendable to use a water-stop-device as for washing machines. The cold water cock must always be opened before setting the unit into operation. During standstill (over night or over the weekend) the cold water cock should be closed.

To avoid sound transmission the cooling water drain hose should be made of heat-resistant rubber material. It must be put over the outlet tube of the vacuum pump and be secured with a hose clamp. The connection with the drain connection must be made by a corresponding rubber bush. The length of the hose must be in a way that the hose cannot slip of the drain connection.

18.4.3 Feed water (operation water)

The connection between apparatus and raw water connection of the deionizer cartridge is done with the plastic hose delivered with unit. At the unit the hose must be connected to the connection after the red cock marked **Filling**. The clean water connection of the deionizer cartridge must be connected with the corresponding hose of the measuring device. The second connection of the measuring device must be connected with the storage tank by a further hose. Care has to be taken that the screwings of the hoses have been tightened and do not drip.

18.4.4 Drain

The local connection for the waste water must be at least 1".

The exhaust of the vacuum pump should be led to the outside. In most cases this is not possible, so that the exhaust is led into canalization together with the condensate and cooling water. This connection should be fixed, if possible. Between the drain inside the unit and the inlet there must be a distance of at least 400 mm, so that the air cannot backwards through the siphon of the drain.

The waste water tubing must be of a heat-resistant material until 80°. Thus it is ideal the put the first 10 to 15 m after the autoclave in metal (cast iron or stainless steel). Afterwards the line can be in commercial plastic tubes. The waste water pipes must be positioned locally in a way that no back pressure can develop.

To avoid sound transmission the cooling water drain hose should be made of heat-resistant rubber material. It must be put over the outlet tube of the vacuum pump and be secured with a hose clamp. The connection with the drain connection must be made by a corresponding rubber bush. The length of the hose must be in a way that the hose cannot slip of the drain connection.

The drain tubes must locally be positioned in a way that a back pressure is not possible.

18.5. Setting into operation after installation

Setting into operation after installation must be executed by our engineers resp. engineers authorized by us or especially trained persons.

Attention: The apparatus main switch may only be switched on **after** the automatic fuses **F1** for heating have been switched off.

The first filling of the boiler with feed water (operation water) after installation or after a standstill of the unit for new setting into operation may only be done when the automatic fuses **F1** for heating have been switched off.

Attention: The heating elements are immediately destructed if they are running dry.

The safety devices can be found in the electric switchboard of the unit, which is locked by the upper apparatus lid. When the lid closure has been unlocked by the special key, the lid can be removed. The electric switch board contains five automatic fuses. The three automatic marked **F1** (heating) must be switched off. Only when these automatic fuses have been switched off, the sterilizer may be switched on at the apparatus main switch.

18.5.1 Removal of accessories from the chamber

When the apparatus has been connected acc. to chapter 18.4 *Connection of operating means*, the cold water valve can be opened and the apparatus main switch be switched on - under consideration of chapter 18.5 *Setting into operation after installation* (switch off the three automatic fuses **F1**). When the LED beyond button **tür** has lighted up, the chamber door can be unlocked and opened by pressing this button and simultaneously swivelling the door lever in direction to the middle of the door. Afterwards all things have to be removed from the chamber and the setting into operation can be continued acc. to chapter 18.5.

18.5.2 Filling of boiler with feed water (operation water)

Attention: Control the water outlet valve for boiler water, resp. close it.

By continuous pressing of button **f2** (LED of this button illuminated) the boiler is filled via the feeding pump with feed water (operation water) from the storage tank. The filling process must be controlled by observing the green ball in the water level glass. An overfilling of the boiler with feed water (operation water) over the max. marking must in any case be prevented.

After the filling process the sterilizer must be switched off at the apparatus main switch and the three safety cut-outs "F1" must be switched on again. When the housing lid is put on again and locked, the apparatus can be switched on again at the apparatus main switch. Thus the heating-up of the boiler water to the operation temperature (approx. 137 °C) starts.

Danger: When touching *electrically conductive* elements there is danger to life !

Hint: As the micro heating element is active during the filling process, it is possible that the water shortage protection switch (overheat protection device) reacts. This reaction is indicated in the display by an acoustic signal and the error note **Overheating**. The acoustic signal automatically stops after 1 minute. By pressing button **clear** the signal can be ended prematurely. The reaction of the water shortage protection switch has no influence on the filling process. The water shortage protection switch must be reset after the filling of the boiler. This is done by pressing the push-button below the apparatus main switch (if necessary, remove the screw cap before). When the push-button snaps in, the error note must be confirmed by pressing button **clear**.

19. Disposal

19.1. Disposal by the manufacturer

The disposal of the apparatus after final shutdown can be done by Messrs. KSG free of charge. The costs arising for dismounting and transportation should be clarified with KSG before.

19.2. Disposal by a special enterprise

The disposal of the apparatus by a local qualified enterprise is possible. The main part of the apparatus can be reused. An appropriate material separation must be guaranteed by the authorized enterprise. Special regulations concerning the disposal of electric or electronic components and cables must be taken into consideration.

***Attention**:* Before transportation of the apparatus the boiler water must be let off completely.

***Danger**:* Before squeezing off the electric line the local main switch must be switched off and be secured against switching on again. For this reason the local safety cut-outs and/or the fault current protection switch (FI) must be switched off and secured against switching on, resp. the safety insets must be removed.

***Attention**:* The local cold water main cock must be closed before dismounting the cold water line.

20. Optional

20.1. Ion Exchange System

20.1.1 Preparation of feed water (operation water)

The ion exchange system, necessary for producing the generator water, is integrated into the sterilizing unit. It consists of one indicating instrument for conductivity, one conductivity meter and one demineralization cartridge. A hose systems connects the different parts to one operating group.

The display of the indicating instrument is only actual **during** the filling process. The scale consists of a number identification and a two-colour beam indication. After a correct installation of a new cartridge the pointer must deflect to the right during the filling process. During the increasing exhaustion of the cartridge the max. deflection of the pointer is shortened corresponding to a decrease of feed water quality. The used cartridge should be replaced latest when a conductivity of 5 µs/cm is reached, as this leads to an important protection of the sterilizing containers and instruments. This is also valid for all stainless steel materials of the unit, which are in contact with the water resp. the steam produced from the water. When changing the cartridge, please proceed acc. to the operating instructions of the manufacturer. Before dismounting the hose connections of an exhausted cartridge, it is absolutely necessary to close the red ball valve marked **filling**.

20.1.2 Deaeration of the ion exchanger cartridge

The following procedure – not included in the operating instructions of the manufacturer – must be strictly followed:

When all hose connections have been made, the deaeration valve (screw made of brass) on the cartridge has to be opened by approx. 2 turns. To prevent that water runs out during the dearation, the clean water hose must be buckled V-shaped and pressed in this position. Afterwards the red manual valve marked **filling** must be opened slowly. Now the raw water is running into the cartridge and displaces the air in the cartridge via both deaeration openings at the deaeration valve. The deaeration procedure has to be continued until bubble-free water is escaping at the openings. Afterwards the deaeration valve and the manual valve have to be closed in this sequence and the feed water (clean water) hose be released.

The durability of the cartridge is mainly depending on the quality and the condition of the raw water on site.

In case of raw water quality 1° dH (1 degree German hardness) complete salt contents the exchange capacity of the cartridge is approx. 10 x litre contents of cartridge type.

Example:

Type 2000	at	1° dH GSG (Complete salt contents)	= 20 000 Litres exchange capacity
	at	5° dH GSG (Complete salt contents)	= 4 000 Litres exchange capacity
	at	10° dH GSG (Complete salt contents)	= 2 000 Litres exchange capacity

(1° dH GSG corresponds to approx. 30 µs)

20.1.3 Series connection of two ion exchanger cartridges

For producing salt-free feed water (operation water) we recommend the use of two cartridges.

Both cartridges have to be connected as follows:

1. At the entry (raw water connection = of the first cartridge the cold water connection has to be placed.

2. The exit (clean water connection) of the first cartridge has to be connected with the entry of the measuring station.

3. The exit of the measuring station has to be screwed with the entry (raw water connection) of the second cartridge.

4. The exit (clean water connection) of the second cartridge has to be connected with the storage tank.

Care has to be taken that the screwings of the connection hoses are screwed pressure-proof. After the connection of all connection a function and sight control has to be effected. The connection markings raw water – clean water at the cartridges have to be considered.

The measuring station measures the conductivity value of the first cartridge. At a conductivity value of **40 µS** the first cartridge should be replaced by the second one. For the second cartridge a new or regenerated cartridge should be used.

After each exchange the deaeration procedure as described in chapter 20.1.2 (Deaeraton of the ion exchanger cartridge) has to be executed starting always with the first cartridge.

Hint: The pointer instrument of the conductivity meter only shows the real conductivity value of the water during the filling process of the storage tank when the unit is switched on.

The use of two ion exchanger cartridges in series offers and optimum and favourable possibility to prepare the generator feed water (operation water) for the production of sterilization steam. As a successful sterilization is also depending on the quality of the steam, the best possible condition of the feed water (operation water) must be guaranteed.

21. Technical Information

Apparatus data

	ED = Self-generated steam	**FD = Domestic steam**
Dimensions (h x w x d) Without Cabinet – Table top	920 x 680 x 740 (without door handle) 920 x 680 x 815 (with door handle)	920 x 680 x 740 (without door handle) 920 x 680 x 815 (with door handle)
Dimensions (h x w x d) With Cabinet – H = 800 mm	1550 x 680 x 740 (without door handle) 1550 x 680 x 815 (with door handle)	1550 x 680 x 740 (without door handle) 1550 x 680 x 815 (with door handle)
Area of installation in m^2	0,51	0,51
Chamber dim. (h x w x d)	220 x 220 x 450 mm	220 x 220 x 450 mm
Chamber volume	22 Litre	22 Litre
Weight without cabinet wit cabinet	approx. 200 kg approx. 235 kg	approx. 190 kg approx. 225 kg
Operation weight without cabinet wit cabinet	approx. 210 kg approx. 245 kg	approx. 200 kg approx. 235 kg

Electrical connection

	ED = Self-generated steam	**FD = Domestic steam**
Kind of current	Rotary current	Rotary current
Voltage Lowest / highest value	3 x 230/400 V - N – PE	3 x 230/400 V - N – PE
Nominal frequency Lowest / highest value	50 / 60 Hz	50 / 60 Hz
Continuous power in kW Lowest / highest value	/ 7,5 kW	/ 3,0 kW
Safety device at site	3 x 20 A	3 x 16 A

Steam

	ED = Self-generated steam	**FD = Domestic steam**
Layout capacity:	39 kg/h	50 kg/h
Steam need:	10 kg/h	10 kg/h
Steam consumption:	5 kg/h	5 kg/h
Steam supply pressure: Lowest / highest value	2,4 / 2,5 bar	2,5 / 2,8 bar
Domestic steam supply connection		25 DN

Feeding water

	ED = Self-generated steam	**FD = Domestic steam**
Highest degree of hardness:	15	Clean steam
ph-value:	5 – 7	
Max. conductibility:	5 µS/cm	
Need of feeding water l/h	4 Litres	5 Litres

Cold water

	ED = Self-generated steam	**FD = Domestic steam**
Cold water connection	½”	½”
Operating pressure of cold water Lowest / highest value	3 / 5 bar	3 / 5 bar
Flow at 3 bar		

Consumption values per cycle

		ED = self-generated steam / FD = Domestic steam			ED = Self-generated steam
		Cycle time	Cold water consumption in litres	Steam consumption in kg	Feeding water consumption in litres
First filling					18
Program 1	Standard	approx. 35 min.	50 – 70	3	3
Program 2	Special	approx. 50 min.	110 – 120	4	4
Program 3	Thermolabile	approx. 55 min.	90 – 120	4	4
Program 4	Vacuum test	approx. 30 min.	30 – 50	2	2
Program 5	Bowie & Dick - test	approx. 30 min.	50 – 70	3	3
Program 8	Empty cycle	approx. 25 min.	50 – 70	2	2

The cycle times of the sterilizing programs are valid when the chamber is fully loaded.

Drain

	ED = Self-generated steam / FD = Domestic steam	
Condensate and cold water	1” - 1½”	
Max. flow	20 litres / min.	
Max. temperature	100° C	

Chamber door

	ED = Self-generated steam / FD = Domestic steam	
Swivel door with one-hand closure		
Max. swivel range	approx. 90°	
Max. swivel area	ca. 33 cm	

Surrounding conditions

	ED = Self-generated steam / FD = Domestic steam		
	Operation	Storage / Transportation	
Temperature	5° - 21° C	5° C – 55° C	
Pressure	950 – 1050 mbar	600 – 1200 mbar	
Air humidity	0 – 55 % rel. humidity	0 – 65 % rel. humidity	

Technical Parameter

	ED = Self-generated steam		**FD = Domestic steam**	
	Steam generator Room I	Pressure vessel Room II	Pressure vessel Room I	Pressure vessel Room II
Contents	15,6 litres	22 litres	15,6 litres	22 litres
Contents up to nominal height	4,0 litres			
Contents up to max. height	9,1 litres			
Permissible operating overpressure	3,0 bar	-1 - +2,5 bar	3,0 bar	-1 - +2,5 bar
Permissible operating temperature	143° C	138° C	143° C	138° C
Max. working temperature		123° C / 137° C		123° C / 137° C
Test pressure (water)	4,0 bar	3,25 bar	4,2 bar	3,25 bar
Medium	distilled water / steam	Steam	Steam	Steam
Kind of heating	electrical		domestic steam	
Heating capacity	6,5 kW			
Steam production	10,0 kg/h			

Construction requirement

TRD, TRB - AD pages	
All sterilizers of type **KSG FLASH-2-ED/FD** fulfil, as far as applicable, the following national and European standards:	
MDD 93/42 EWG	Recommendations and directives of the Council of Europe
EN 61010-2-041	Safety regulations for electrical measuring, control, regulating and laboratory units
EN 61010-1 and 1/A2	Safety regulations for electrical measuring, control, regulating and laboratory units
DIN EN 50 051-1/2	Electromagnetic compatibility – Interfering transmission
DIN EN 50 052-1/2	Electromagnetic compatibility – Interfering solidity
DIN EN 46001	Medical products (Quality securing systems)
DIN 58946-6 (Draft)	Steam sterilizers (Sterilization)
DIN EN 554	Sterilization of medical products: Validation and routine maintenance for the sterilization with moist heat
DIN EN 285	Steam sterilizers – Large sterilizers (Sterilization)
VBG 4	Electrical plants and operating means (Accident-preventing regulations)
VBG 1	General regulations (Accident-preventing regulations)

22. Maintenance check list

Maintenance and check - daily KSG FLASH-2

Month: ..... Year:.....

Day	Signature
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1. Maintenance/control of door gasket :

Chapter 15.1 Care of the door gasket.

Remove gasket from gasket groove.
Clean gasket and gasket groove.
Check gasket on damages and ageing (if necessary, renew gasket).
Grease gasket (special silicone fat) and insert it into the gasket groove.

2. Visual and Readiness check:

Control chamber door closure mechanism on wear / damages.

Control inner chamber on remainders and sediments and clean it.
See chapter 15.2 Cleaning and care of the chamber.

Indicating instruments: Control zero position of pointer-pressure, temperature.

Control of operation means: Cold water inlet, current supply.

Control of feeding water quality during the filling of the storage tank.
Visual control at the conductivity meter. Max. value 5 µS/cm at 20° C.

Control of operation readiness: boiler water level, boiler pressure.
Control of operation readiness of registration unit: paper, colour ribbon.
Control of proper operation during the empty cycle.

3. Control of steam penetration:

Bowie & Dick - test (Bowie & Dick simulation test).
The test procedure must correspond to DIN EN 285: 1997-02, section 19, 8.3.2.1, 26.1.5. See chapter 10.3.1 Steam penetration test.

4. Routine checks during daily operation:

Visual control of the operation. Control of the noise during operation. Control of time and measured values during operation.

Treatment of this form:
The form can be multiplied. The use of this form is determined for one calendar month. Month and year must be indicated in the first line. With the signature the operating personal confirms the correct execution of the maintenance and control works acc. to point 1-3. Point 4 does not need a signature. The form must be filed and be presented upon request.

Maintenance and check – weekly KSG FLASH-2

Date: . . Signature: .....

The weekly maintenance and control works have to be executed **additionally** once a week together with the daily maintenance and control works.

1. Cleaning and care of the apparatus casing and the substructure room:

Cleaning and care of the stainless steel casing and the substructure room has to be executed acc. to chapter 15.3 Cleaning of the apparatus casing.

2. Care of the chamber:

Care of the chamber, the inner sides of the chamber door and the sieve trays should be executed acc. to chapter 15.2 Cleaning and care of the chamber.

Treatment of this form:

This form can be multiplied. The use of this form is determined for one calendar week. The date must be indicated in the first line. With the signature the operating personal confirms the correct execution of the maintenance and control works acc. to point 1 and 2. The form must be filed and be presented upon request.

Maintenance and check – monthly KSG FLASH-2

Date: . . Signature: .....

The monthly maintenance and check works must be executed one a month **additionally** to the daily maintenance and check works.

1. Control of boiler water quality:

Removal of boiler water may only be executed at the cold, not heated-up unit.
The pointer of the pressure gauge must be on **0**.
Water removal is done by opening the boiler water outlet valve.
Acc. to DIN 589 46-6 the boiler water must have a conductivity of ≤ 100 µS/cm at 20° C and a mass concentration of SIO_2 ≤ 10 mg/l.

2. Check on vacuum tightness:

The test is done by the vacuum test program. It must be run after having reached the operating pressure of the boiler as first program.
(See chapter 8.4 Test program 4 Vacuum test 125 – 134° C / Check on vacuum tightness).

Treatment of this form:

This form can be multiplied. The use of this form is determined for one calendar month. The date must be indicated in the first line. With the signature the operating personal confirms the correct execution of the maintenance and control works acc. to point 1 and 2. The form must be filed and be presented upon request.

Maintenance and check – every 6 months KSG FLASH-2

Date: . . Signature: .....
Period from . . to . .

The maintenance and check works every six months must be executed by an **authorized** service technician.

1. Maintenance and check every 6 months:

The use must have checked the unit acc. to chapter 16.4.4 – Maintenance every six months – by a service technician.

The volume of the maintenance and check works is determined by form –*Maintenance check list FLASH-2.*

The execution of the maintenance and check works must be entered into the apparatus book.

Treatment of this form:

This form can be multiplied. The use of this form is determined for 6 months. Date and period must be indicated in the first line. With the signature the operating personal confirms the punctual execution of the maintenance works every 6 months. This form must be filed and presented upon request.

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Maintenance Check List KSG 116–2 / 118–2 / Flash-2
Apparatus No.: _____ Year of construction: _____

Maintenance after 400 cycles resp. every six months

Customer:
.....
Address:
.....

- ○ **Check the vacuum pump**
  - decalcify it
- ○ **Renew aeration filter**
  (every six months, acc. to regulations)
- ○ **Boiler water (jacket)**
  - Let off the boiler water and rinse the boiler
- ○ **Door magnet**
  - Check on function
  - Good mobility
- ○ **Check water shortage function**
  - Switch off thermal cut-out (F1)
  - Switch on apparatus and wait
  - The display must show
  Overheat protection device“
- ○ **Check flap trap**
- ○ **Setting into operation**
  - Check heating capacity
- ○ **Program run**
  - Run vacuum test
  - Run empty cycle
  - Run Bowie-Dick-Test
- ○ **- Run Program 2 with full load**
  Visual check
  - Check condensate trap upon its function
  - Observe PT 100 during „Sterilization“
- ○ **Check the complete unit upon tightness**
- ○ **Check the regulating, safety and warning devices**
- ○ **Maximum thermometer in the centre of the cassette**
  at 121° value _____
  at 134° value _____
- ○ **Remove dirt traps, clean and reinstall them**
- ○ **Control the valves visually:**
  - Tappet
  - Spring
  - O-Ring
  - Renew valve completely
- ○ **Door closure**
  - Remove door gasket **and clean it**
  - Check door gasket and exchange it, if necessary
  - Check gasket groove**, remove remaining grease**
  - Clean the back side of the door blade from grease
  - Control door closure **visually and grease it, if necessary**
- ○ **Renew boiler water (jacket)**
  - Fill storage tank
  - Observe pointer instrument for demineralisation device = pointer must be in the green area
  - Refilling of the boiler up to max. (observe water level glass)
  - Press overheat protection device
  Switch on thermal cut-out (F1)
- ○ **Check vacuum aggregate**
  - Blow valve
  - Hand valve cold water for vacuum pump
- ○ **Control indicating instruments (pressure, temperature) and readjust them, if necessary**
- ○ **Check control and indicating lamps**
- ○ **Check all pressure points during program cycle upon concrete break-over point and readjust, if necessary**
- ○ **Control electrical and electronical parts as well as binders and readjust them, if necessary**
- ○ **Periodical examination with bio-indicators (acc. to customer’s order)**
- ○ **Control cycle print out**

_____

Signature of customer ..... Date .....

Signature of technician .....